Minutes of the Meeting of the Audit and Compliance Committee of the Board of Directors of the Cook County Health and Hospitals System (CCHHS) held Friday, January 21, 2022 at the hour of 9:00 A.M. This meeting was held by remote means only, due to the determination that a public health emergency exists.

I. Attendance/Call to Order

Chair Koetting called the meeting to order.

Present: Chair Mike Koetting and Directors Ada Mary Gugenheim and Robert G. Reiter, Jr. (3)

Board Chair Lyndon Taylor (ex-officio) and Directors Joseph M. Harrington and Otis L. Story, Sr.

Absent: Hon. Dr. Dennis Deer, LCPC, CCFC (1)

Additional attendees and/or presenters were:

Nicole Almiro - Chief Corporate Compliance and Privacy Officer
Jeff McCutchan – General Counsel
Israel Rocha, Jr. – Chief Executive Officer
Deborah Santana – Secretary to the Board
Tom Schroeder – Director of Internal Audit

The next regular meeting of the Audit and Compliance Committee is scheduled for Wednesday, April 20, 2022 at 9:00 A.M.

II. Electronically Submitted Public Speaker Testimony

There was no public testimony submitted.

III. Report from Chief Corporate Compliance and Privacy Officer (Attachment #1)

Action Items – Receive and File the following reports (Attachment #2):

- CountyCare Compliance Program – FY2021 Annual Report
- Cook County Health System (Provider) Compliance Program – FY2021 Annual Report
- Cook County Research Compliance Program – FY2021 Annual Report

Nicole Almiro, Chief Corporate Compliance and Privacy Officer, provided an overview of the information contained in the Report, and reviewed the three (3) annual reports to be received and filed. The Committee reviewed and discussed the information.

Ms. Almiro provided an update on a pending matter. At a previous meeting, during the discussion of the newly created internal Research Compliance Committee, a question was raised regarding whether a member of the Board should be included as a member of that internal committee. It was determined that there is no need for Board representation; however, this body will continue to receive reports from the Research Compliance Committee and there will be opportunities to discuss the information provided and ask questions.

IV. Action Items

A. Accept Minutes of the Audit and Compliance Committee Meeting, November 5, 2021

Chair Koetting inquired whether any corrections were needed to be made to the Minutes.

B. Any items listed under Sections III, IV and V

Director Gugenheim, seconded by Director Reiter, moved to receive and file the three (3) annual reports included within the Report of the Chief Corporate Compliance and Privacy Officer, and to accept the November 5, 2021 Audit and Compliance Committee Meeting Minutes. On the motion, a roll call vote was taken, the votes of yeas and nays being as follows:

Yeas: Chair Koetting and Directors Gugenheim and Reiter (3)

Nays: None (0)

Absent: Deer (1)

THE MOTION CARRIED UNANIMOUSLY.

V. Closed Meeting Items

A. Report from Director of Internal Audit
B. Discussion of Personnel Matters

Director Reiter, seconded by Director Gugenheim, moved to recess the open meeting and convene into a closed meeting, pursuant to the following exceptions to the Illinois Open Meetings Act: 5 ILCS 120/2(c)(**1**), regarding "the appointment, employment, compensation, discipline, performance, or dismissal of specific employees of the public body or legal counsel for the public body, including hearing testimony on a complaint lodged against an employee of the public body or against legal counsel for the public body to determine its validity," and 5 ILCS 120/2(c)(**29**), regarding "meetings between internal or external auditors and governmental audit committees, finance committees, and their equivalents, when the discussion involves internal control weaknesses, identification of potential fraud risk areas, known or suspected frauds, and fraud interviews conducted in accordance with generally accepted auditing standards of the United States of America."

On the motion to recess the open meeting and convene into a closed meeting, a roll call was taken, the votes of yeas and nays being as follows:

Yeas: Chair Koetting and Directors Gugenheim and Reiter (3)

Nays: None (0)

Absent: Deer (1)

THE MOTION CARRIED UNANIMOUSLY and the Committee convened into a closed meeting.

Chair Koetting declared that the closed meeting was adjourned. The Committee reconvened into the open meeting.

VI. Adjourn

As the agenda was exhausted, Chair Koetting declared the meeting ADJOURNED.

Respectfully submitted,
Audit and Compliance Committee of the Board of Directors of the Cook County Health and Hospitals System

XXXXXXXXXXXXXXXXXXXXXXX
Mike Koetting, Chair

Attest:

XXXXXXXXXXXXXXXXXXXXXXX
Deborah Santana, Secretary

ATTACHMENT #1

Corporate Compliance Report

Audit & Compliance Committee of the CCH Board of Directors

January 21, 2022

COOK COUNTY HEALTH

Meeting Objectives

Review

Highlights of FY 2021

- Metrics
  - Year-Over-Year Comparison
  - Contacts by Category
    - Cook County Health Compliance Program
    - CountyCare Medicaid Health Plan Compliance Program
      - Recoveries
    - Cook County Health Research Compliance Program
- Receive and File – Annual Reports
  - Cook County Health
  - CountyCare
  - Cook County Health Research

Facing Forward – 2022 Compliance Work Plan

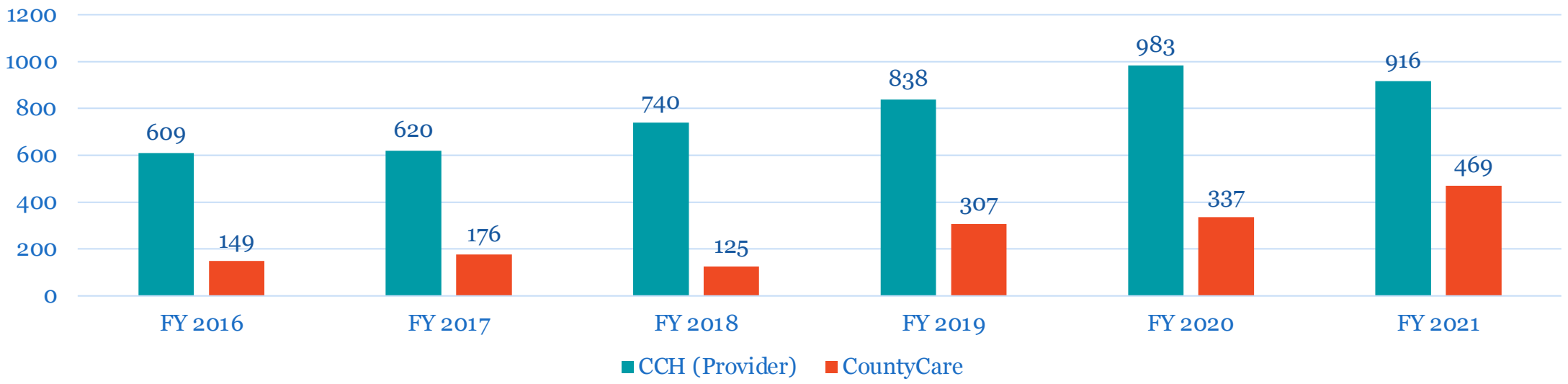
Metrics

Highlights of the Annual Reports

COOK COUNTY HEALTH

Year-Over-Year Compliance Program Contacts

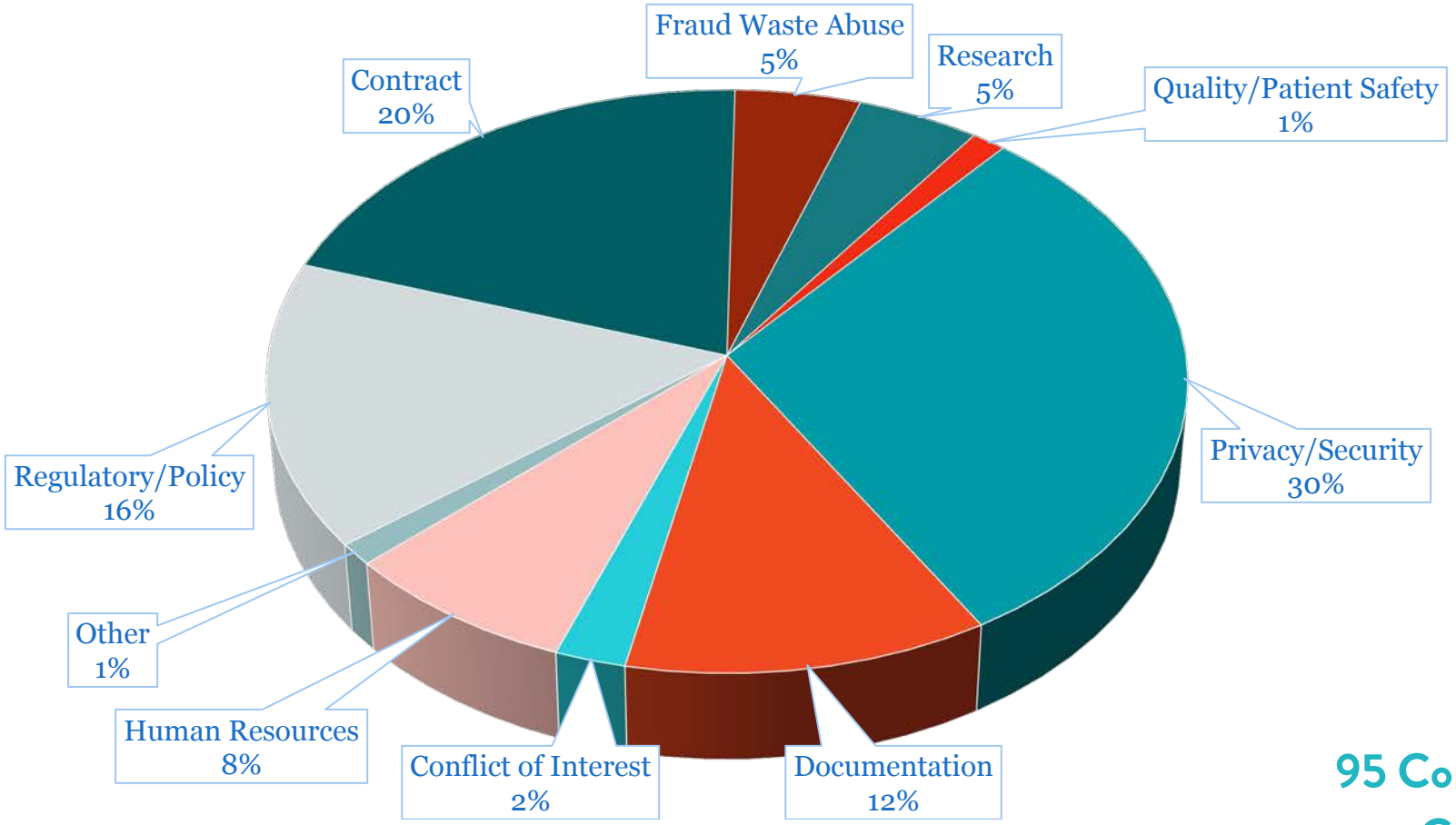
CCH System Compliance and CountyCare Health Plan



COOK COUNTY HEALTH

FY 2021 Contacts by Category

CCH System Compliance Program



12/01/2020 – 11/30/2021

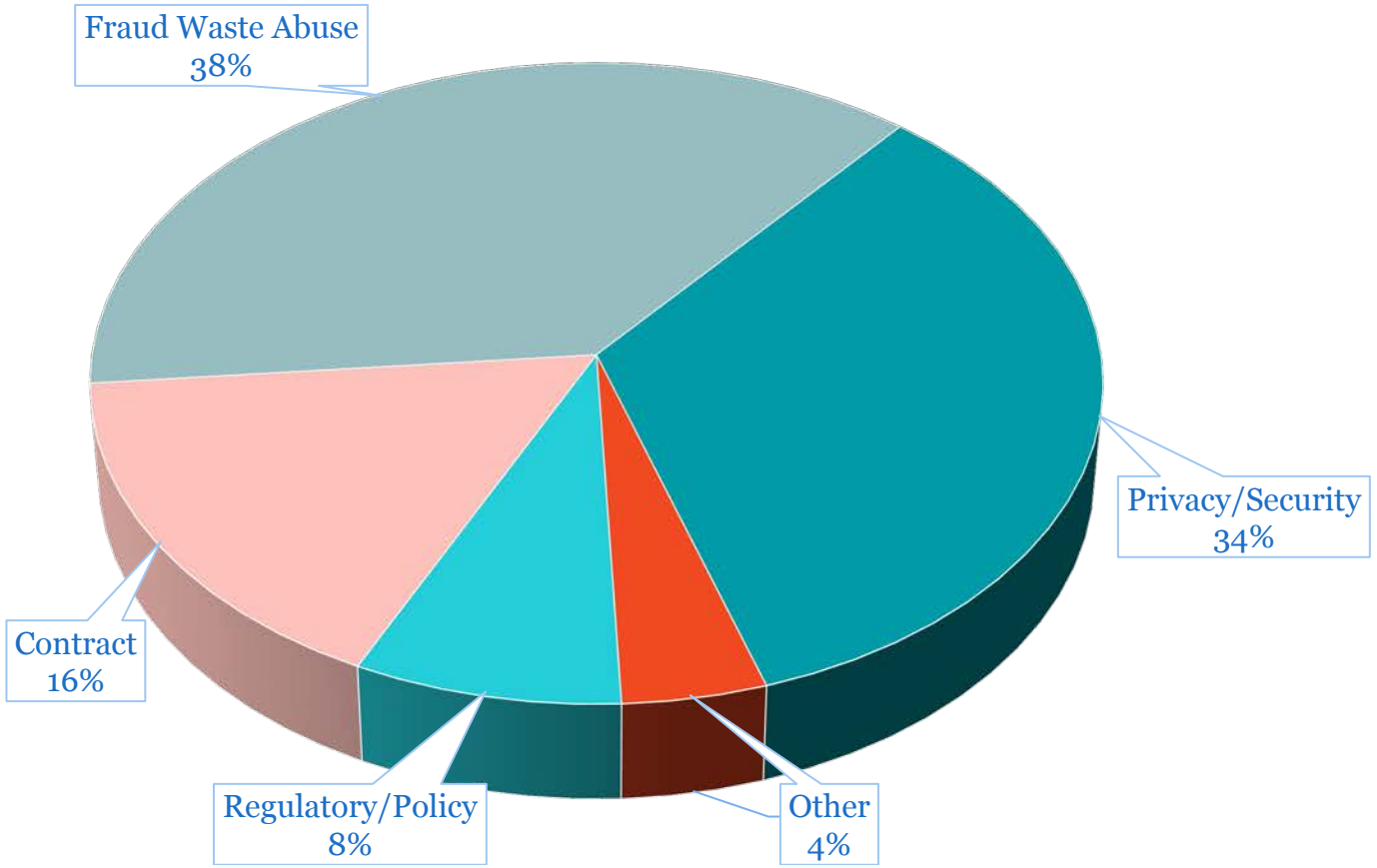
Categories	
Privacy/Security (HIPAA)	278
Contracts	184
Regulatory/Policy	145
Documentation	108
Human Resources	70
Fraud Waste & Abuse	44
Research	43
Conflict of Interest	21
Quality/Patient Safety	12
Other	11
	916

95 Contacts (10%) were COVID-19 Related

COOK COUNTY HEALTH

FY 2021 Contacts by Category

CountyCare Health Plan Compliance Program



12/01/2020 – 11/30/2021

Categories	
Fraud Waste & Abuse	176
Privacy/Security (HIPAA)	159
Contracts	77
Regulatory/Policy	37
Other	20
TOTAL	**469**

4 Contacts (<1%) were COVID-19 Related

COOK COUNTY HEALTH

CountyCare Fraud, Waste and Abuse Recovery Metrics

State Fiscal Year (S-FY) 2021 through S-FY 2022 Q1

S-FY	Reporting Period	Tips[1]	Referrals to HFS OIG	Overpayments Identified[2]	Overpayments Collected
2021	Q1 07/01 -09/30/20	49	0	$ 1,277,500	$ 196,600
2021	Q2 10/01 – 12/31/20	106	8	$ 1,697,500	$ 304,000
2021	Q3 01/01 – 03/31/21	49	20	$ 1,970,360	$ 713,020
2021	Q4 04/01 – 06/30/21	46	9	$ 1,378,755	$ 485,839

S-FY	Reporting Period	Tips	Referrals to HFS OIG	Overpayments Identified	Overpayments Collected
2022	Q1 07/01 – 09/30/21	100	18	$ 583,637	$ 66,066

Proactive Preventative Loss

S-FY	Reporting Period	Overpayments Collected
2021	Q1 07/01 -09/30/20	$ 333,400
2021	Q2 10/01 – 12/31/20	$ 716,000
2021	Q3 01/01 – 03/31/21	$1,112,186
2021	Q4 04/01 – 06/30/21	$1,206,723

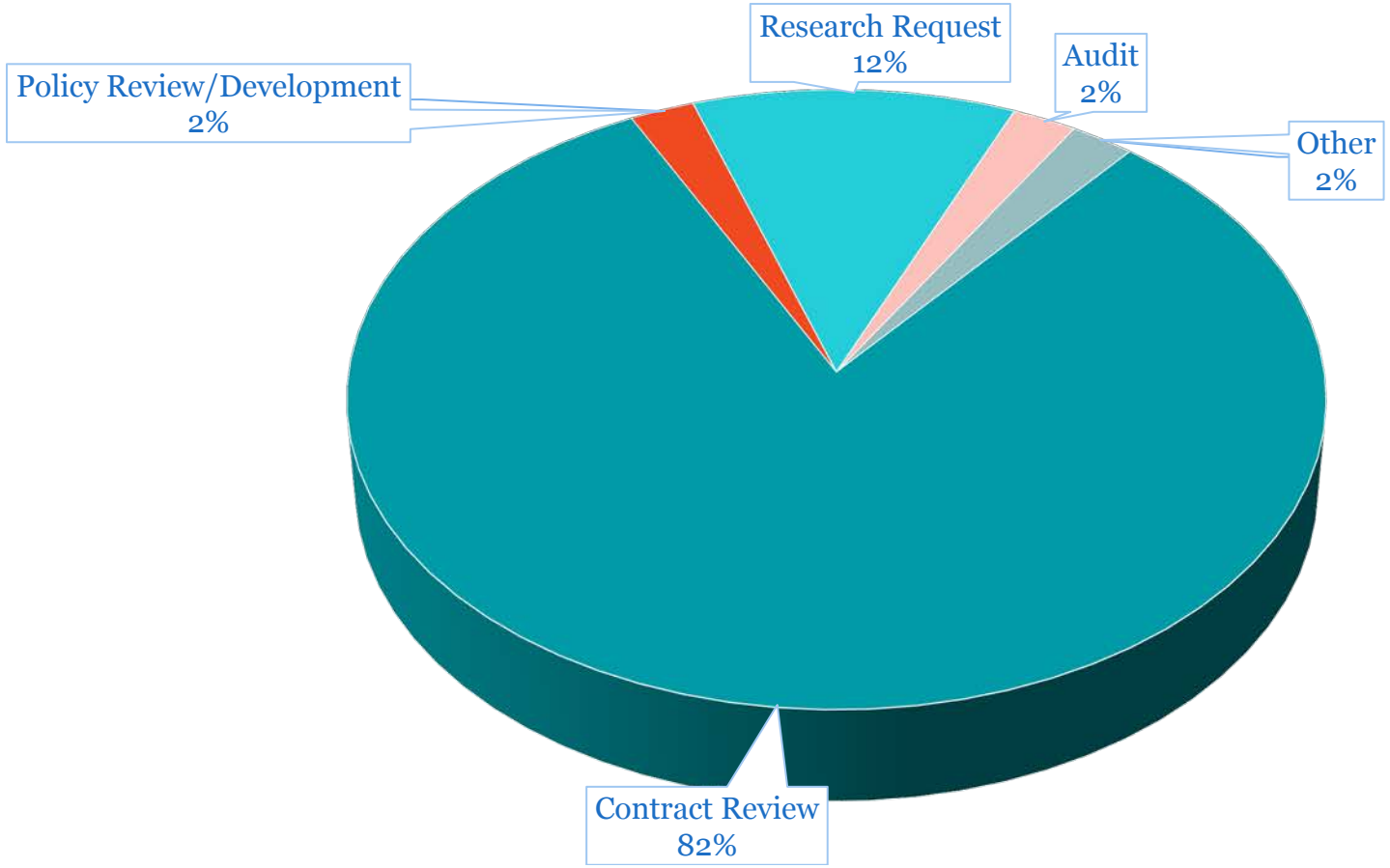
S-FY	Reporting Period	Overpayments Collected
2022	Q1 07/01 – 09/30/21	$1,029,151

[1] The term ***Tip*** as defined by HFS OIG includes any allegations or incidents of suspected FWA opened on a CountyCare provider. A tip is a preliminary identification of a potential concern.

[2] The ***Overpayments Identified*** column indicates the currently outstanding amount that has been paid to a provider for identified inaccurate codes. These amounts may be supported through additional review of documentation submitted by the provider or may be offset if a provider elects to bill a corrected claim.

FY 2021 Contacts by Category

Research Compliance Program



12/01/2020 – 11/30/2021

Categories	
Contract Review	35
Research Request	5
Audit	1
Policy Review/Development	1
Other	1
TOTAL	**43**

COOK COUNTY HEALTH

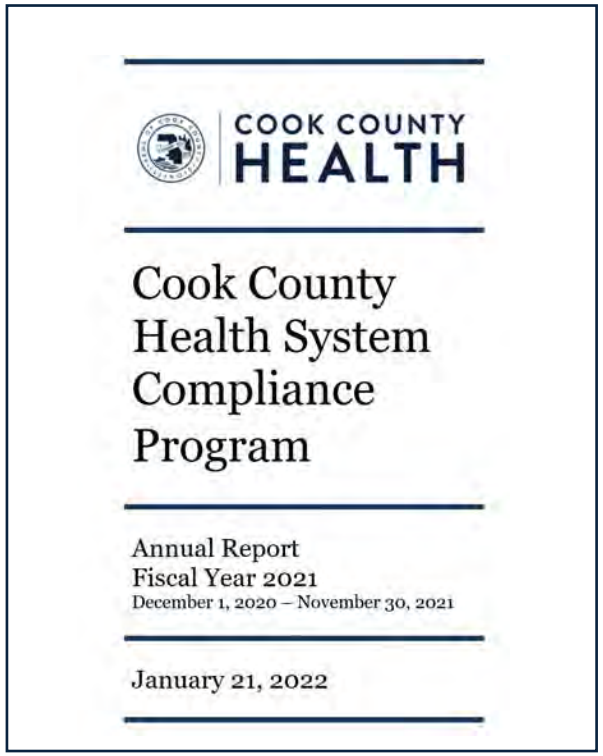
Receive and File

Annual Reports

COOK COUNTY HEALTH

Corporate Compliance Annual Reports

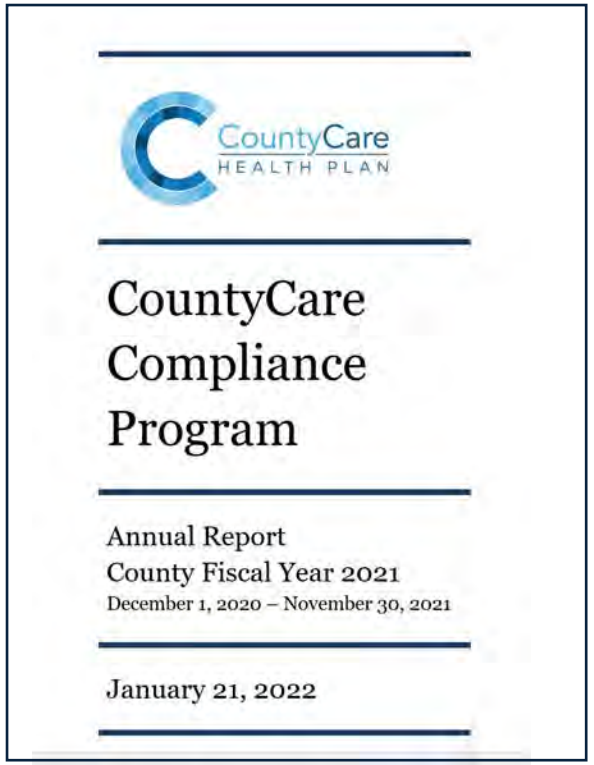
CCH System Compliance Program and CountyCare Medicaid Plan Compliance Program


COOK COUNTY HEALTH

Cook County Health System Compliance Program

Annual Report
Fiscal Year 2021
December 1, 2020 – November 30, 2021

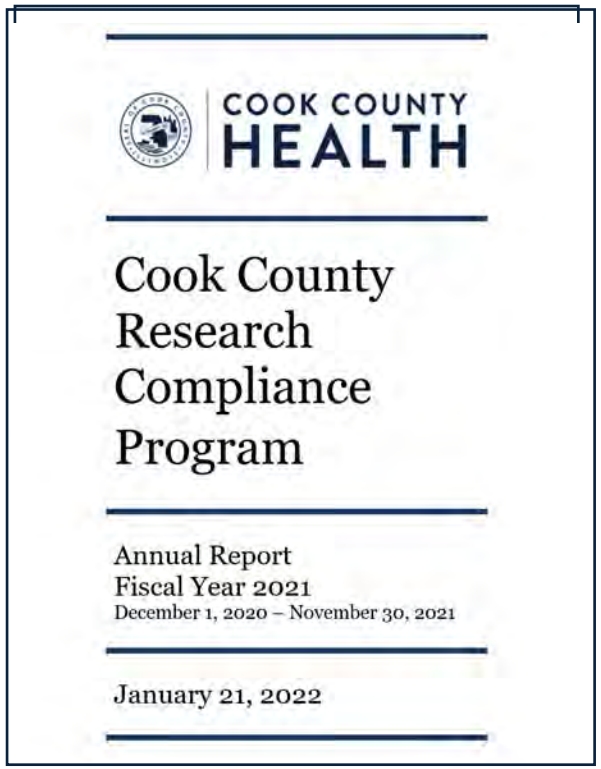
January 21, 2022


CountyCare HEALTH PLAN

CountyCare Compliance Program

Annual Report
County Fiscal Year 2021
December 1, 2020 – November 30, 2021

January 21, 2022


COOK COUNTY HEALTH

Cook County Research Compliance Program

Annual Report
Fiscal Year 2021
December 1, 2020 – November 30, 2021

January 21, 2022

Facing Forward

FY 2021 Work Plan

COOK COUNTY HEALTH

Facing Forward

2022 Corporate Compliance Work Plan

In addition to continued administration of the essential elements of the Corporate Compliance Program, (1) standards of conduct and policies; (2) oversight responsibilities; (3) education and training; (4) mechanisms for reporting; (5) enforcing standards; (6) monitoring and auditing; and (7) prevention,

Corporate Compliance will embark on the following key initiatives in 2022:

- Development of Animated Educational Videos
- Continued Development of the Research Compliance Program
- Advancement of Clinical Documentation Education Program
- Implementation of Recommendations for Improvement from External Effectiveness Evaluation

Questions?

COOK COUNTY HEALTH

ATTACHMENT #2

CountyCare Compliance Program

Annual Report
County Fiscal Year 2021
December 1, 2020 – November 30, 2021

January 21, 2022

Table of Contents

I. Executive Summary....3
II. Introduction....5
III. Building Blocks – Program Infrastructure and Scope....6
IV. Continued COVID-19 Related CountyCare Compliance Activity....9
V. Annual Compliance Program Activity - Performance of the Elements....10
Element 1 - Standards of Conduct, Policies and Procedures....10
Element 2 - Compliance Office and Oversight Responsibilities....13
Element 3 - Education and Training....17
Element 4 - Receiving and Responding to Complaints....18
Element 5 - Enforcing Standards....23
Element 6 - Monitoring and Auditing....25
Element 7 – Prevention....28
VI. Looking Ahead to 2022....30

I. Executive Summary

As a public, provider-led health plan, we improve our members' lives by partnering with communities, supporting a vibrant safety-net, advancing health equity, and empowering providers to deliver integrated, member-centered health care.

The Cook County Fiscal Year ("CFY") 2021 CountyCare Compliance Program Annual Report summarizes the compliance activities carried out in CFY 2021, as well as identifies priorities for CFY 2022.

This past fiscal year, CountyCare Health Plan ("CountyCare") accomplished many goals and implemented a variety of initiatives despite several hardships and challenges. The Cook County Health Corporate Compliance Program ("CCH Compliance") dedicated to CountyCare was directly involved in each major initiative to ensure execution adhered to and incorporated relevant regulatory directives and contractual requirements. Some achievements include:

- Selection of a New Designated Compliance Officer
  CCH Compliance brought on both a new Chief Compliance Officer and new designated Compliance Officer for CountyCare. Both onboarded at the end of September 2021. The new CountyCare Compliance Officer will provide CountyCare with consistent and stable Compliance leadership going into the new fiscal year and beyond.

- CountyCare Remained the Largest Medicaid Health Plan in Cook County
  At the close of CFY 2021, CountyCare remained the largest Medicaid Health Plan in Cook County for the fourth year in a row. As of December 2021, CountyCare covered more than 422,000 lives. Membership growth continues on an upward trajectory with 9,400 new enrollees joining CountyCare in December 2021 alone. This growth is aided by the State of Illinois increasing auto-enrollment of 50% of incoming Medicaid recipients to CountyCare because of CountyCare's excellent quality of care score.

- COVID-19's Continued Impact
  CountyCare continued to provide a comprehensive COVID-19 response through the second year of the COVID-19 pandemic. Partnering with CCH, this included a national award-winning multimedia advertisement and education campaign, standing up one of the nation's largest community COVID-19 vaccination programs, administering more than 918,000 doses, implementing COVID-19 vaccine incentives, continuing targeted member outreach, home delivered meals program, patient monitoring, developing a flexible housing pool benefit, enhanced transportation, etc.

- Proactive Monitoring and Auditing
  CountyCare Compliance identified opportunities to become more proactive in its monitoring and auditing of potential fraud, waste, and abuse. This included being more involved at the initial contracting level and strongly partnering with the Delegated Vendor Oversight team to audit vendors and their compliance programs. These efforts allow CountyCare Compliance to continue focusing on maintaining adherence to contractual

requirements and healthcare compliance best practices as the program continues to mature and be a publicly recognized brand.

- Collaboration with Special Investigation Units ("SIUs") for Payment Integrity Initiatives
  CountyCare Compliance Program Integrity activities resulted in a total of approximately $1.7 million collected in overpayments in state Fiscal Year ("SFY") 2021 and proactively prevented $3.37 million in losses. Recovery amounts continue to be impacted by the recoupment hold put in place at the onset of the Public Health Emergency ("PHE") and the implementation of prior approval processes by HFS OIG for all recoupment activity. Approximately $8.3 million in pending recoveries will be processed by CountyCare's SIU in CFY 2022 that were identified during the August 2020 – August 2021 timeframe using data mining and clinical audits.

- Supported planning and initial implementation of MMAI line of business
  Continuing with its growth trajectory, Health Plan Services is exploring the possibility of adding a new MMAI line of business to help streamline continuity of care for certain eligible member populations. While MMAI is subject to different laws, regulations, and rules, CountyCare Compliance has actively worked with CountyCare leadership and operational staff to support the potential future line of business.

- Strengthened Relationship with State Partners
  In 2021, Illinois Department of Healthcare and Family Services ("HFS") Office of the Inspector General ("OIG") transitioned to new leadership under Inspector General Brian Dunn. CountyCare continues to develop and foster an excellent relationship with state partners and look forward to the new perspectives and processes Inspector General Dunn will implement.

In CFY 2022, CountyCare Compliance will continue to focus on maintaining adherence to contractual requirements and healthcare compliance best practices, as both the Health Plan and compliance program continue to build upon and mature under the direction of new leadership. CountyCare Compliance also recognizes the significant support from CCH Compliance and will continue to resume functions CCH Compliance supported exclusively in CFY 2020 and a majority of CFY 2021. In collaboration with its delegated vendors, CountyCare Compliance will concentrate on identifying opportunities for risk reduction in the areas of compliance, policy implementation, and the development and implementation of monitoring and auditing efforts.

Notable priorities that have been identified for CFY 2022 include:

- CountyCare Compliance Officer Onboarding
  Training and continued onboarding of the new designated Compliance Officer for CountyCare and increased effort to locate additional resources for CountyCare Compliance to better concentrate on initiatives designed to improve the Compliance Program, Program Integrity, and compliance presence for CountyCare operations.

- Workforce Education and Compliance Training
  Increase CountyCare workforce education and knowledge regarding CountyCare Compliance's duties, the compliance hotline, and a workforce member's duty to report, to encourage proactive identification and discussion of issues with the department.

- Strengthen Partnerships with Special Investigation Units ("SIUs") for Payment Integrity Initiatives
  Continue to strengthen processes for Program Integrity oversight in the areas of fraud, waste, abuse, mismanagement and misconduct (collectively, "FWA"), in collaboration with vendor partners. A key priority in CFY 2022 will be the continued recovery of claims from the HFS OIG preliminary claim recovery hold due to the PHE.

- Increase collaboration with key stakeholders
  Strengthen and enhance collaboration with CountyCare Delegated Vendor Oversight program to develop more comprehensive and strategic annual compliance related audits of vendors. Additionally, continue to work collaboratively with HFS, HFS OIG, non-government organizations and other Managed Care Organizations' SIUs to build a network of skilled investigators and increase effective Program Integrity efforts.

- Improved reporting
  As an organization with a highly delegated operational model, nimble, efficient, reporting is crucial for strong governance and oversight. CountyCare Compliance will review and leverage existing and new systems and tools to improve the quality of reporting across the various delegated partners with whom CountyCare has relationships.

II. Introduction

CountyCare is a Managed Care Community Network ("MCCN") health plan offered by Cook County Health ("CCH") pursuant to a contract with the Illinois Department of Healthcare and Family Services ("HFS"). Since late 2012, CCH has partnered with the State of Illinois, initially through the State of Illinois federal Section 1115 demonstration waiver which was an early start on Medicaid expansion, then in 2014, CountyCare transitioned into the MCCN. The operation of the CountyCare MCCN is facilitated through CCH and its various subcontractors.

To adhere to the Medicaid Managed Care Program Integrity requirements outlined by both Centers for Medicare & Medicaid Services ("CMS") and the contractual provisions in the MCCN Agreement with HFS, as well as the elements of an effective compliance program as recommended in the Department of Health and Human Services Office of Inspector General ("OIG") Compliance Program Guidance publications, CCH developed and implemented the CountyCare Compliance Program.[1] The CountyCare Compliance Program is designed to demonstrate the Health Plan's

[1] See 42 C.F.R. §438.608 and Section 5.35 of the MCCN Agreement (2018-24-201), as amended by KA2 and KA5 in 2020. See also HHS OIG Compliance Guidance documents linked here.

ongoing commitment to promoting ethical and lawful conduct consistent with all applicable laws, regulations, contractual requirements, CCH policies, procedures, and Code of Ethics.

This Annual Report presents the activities during County Fiscal Year ("CFY") 2021 covering December 1, 2020 through November 30, 2021. Effective late-September 2021, CountyCare Compliance is under the executive leadership of Nicole Almiro, Chief Compliance & Privacy Officer, Ashley Huntington, Privacy Officer, and John Tao, Compliance Officer, CountyCare, with outgoing Chief Compliance & Privacy Officer and Interim CountyCare Compliance Officer Cathy Bodnar's departure in November 2021. Cathy Bodnar's years of service and dedication to CCH is highly admired and will be greatly missed. CountyCare Compliance functions are supported by two (2) Compliance Analysts from CCH Compliance. CCH and CountyCare Compliance continues to engage external compliance consultants from Strategic Management, LLC to assist with critical CountyCare projects, support leadership transitions, and temporarily fill staffing openings, as necessary, for CCH and CountyCare Compliance.

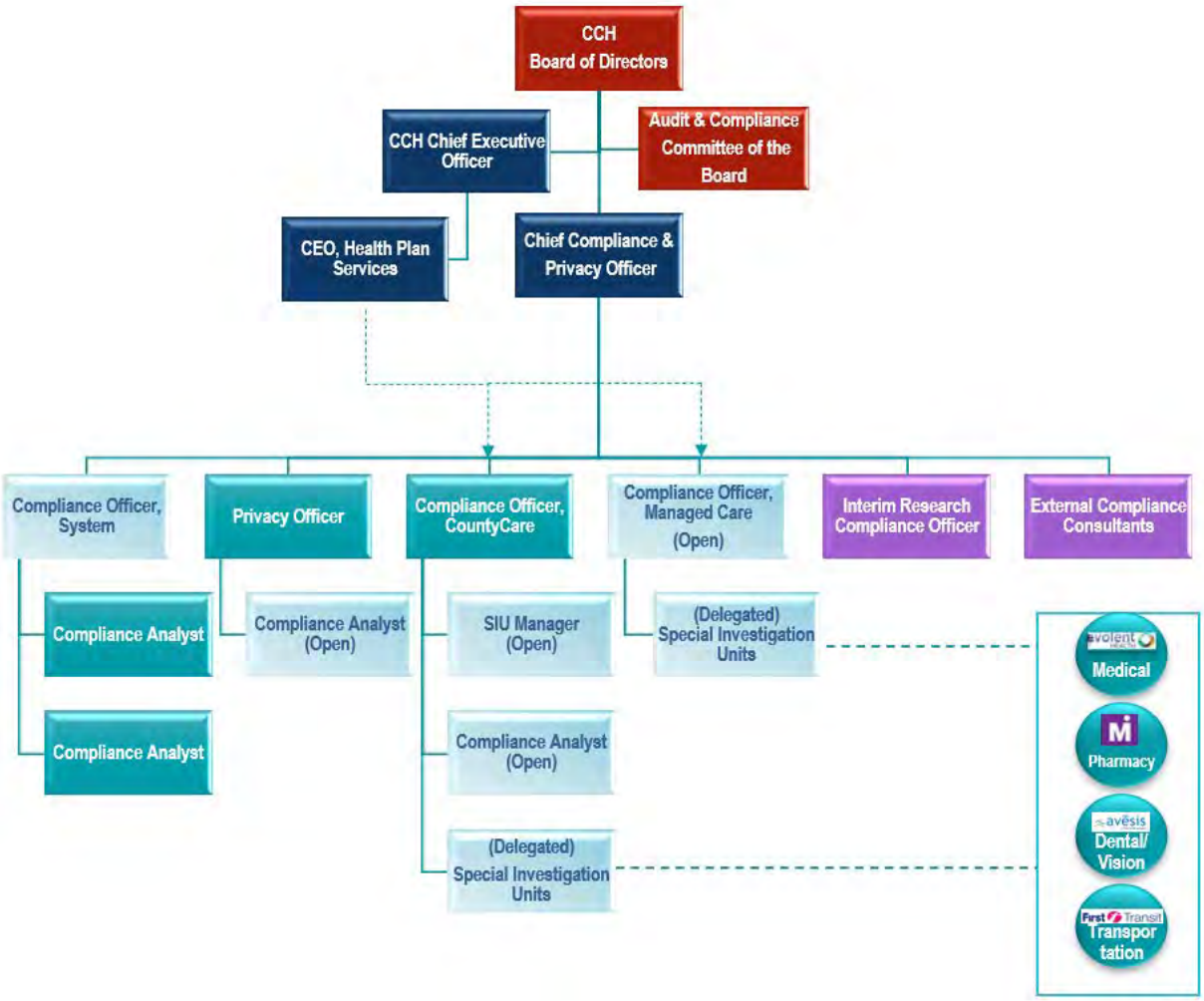
III. Building Blocks – Program Infrastructure and Scope

This Annual Report begins with a look at the structure and activities of CCH and CountyCare Compliance generally, which includes the infrastructure supporting a comprehensive compliance program for CountyCare and its affiliates.

CountyCare Compliance Program Infrastructure

The current CCH Compliance Departmental Organization Chart appears below.

CCH Compliance Organization Chart



Adequate resourcing for the CountyCare Compliance Program remained a significant challenge in CFY 2021 and will continue to be a priority in CFY 2022. Excitingly, the Compliance Officer, CountyCare role was finally filled at the end of September 2021. However, due to CFY 2020 CCH budget staff reduction, and CCH Compliance having eliminated two Compliance Analysts positions, continued CCH and CountyCare Compliance resource strain remains a significant challenge. Four CCH Compliance positions remain open at this time (see chart, above). Efforts to fill open positions are a critical priority for CCH Compliance in CFY 2022.

Due to significant staffing shortages, CCH Compliance continued its interdepartmental workload redistribution, with a majority of CountyCare Compliance issues being exclusively managed by CCH Compliance during CFY 2020 and the majority of CFY 2021. Specifically, CCH Compliance continued managing all Privacy related issues for CountyCare, including: breach analysis and notification; data sharing requests and guidance; subpoena and subrogation requests; Provider Alerts and Stand Down Notices; and, both coordinated and participated in regular leadership,

delegated vendor, and CountyCare regulator meetings. CCH Compliance also continued its engagement with longtime department consultants, Strategic Management, LLC to assist with critical CountyCare and Privacy projects and support the overall success of CCH Compliance. Consultants from Strategic Management continue to provide staffing support for the department while a longer term, sustainable, option is considered. With a new CountyCare focused Compliance Officer onboarded, emphasis has been prioritized on continuing to fulfill the comprehensive slate of required FWA audit, investigation, and reporting responsibilities mandated by the Program Integrity provisions of the MCCN agreement; where possible, CountyCare Compliance also engaged in identifying and addressing CountyCare Compliance related issues as reported, in both a proactive and reactive manner.

CCH and CountyCare Compliance's limited staffing has resulted in the necessity to focus only on core elements of the Compliance Program, including those activities mandated by the MCCN Agreement and required by HFS and HFS OIG.

CountyCare Compliance Program Scope

The CountyCare Compliance Program is tasked with outlining guidelines and providing insight to:

- Comply with the CMS Managed Care Program Integrity requirements and the terms of the CountyCare Health Plan contract with HFS;
- Prevent, detect, and eliminate fraud, waste abuse, mismanagement and misconduct (collectively "FWA");
- Protect CountyCare members, providers, CCH, the State, and the taxpaying public from potentially fraudulent and/or unethical activities;
- Respond and provide guidance related to privacy, confidentiality, and potential or actual security breaches;
- Provide high level oversight to CountyCare's Grievances and Appeals Program; and,
- Understand and focus on high-risk areas that have the greatest potential for non-compliance with federal and state regulatory and contractual requirements.

The following types of activities and issues fall into the CountyCare Compliance Program purview:

- Interpretation of contracts, laws, rules, regulations, and organizational policy as they relate to CountyCare Compliance;
- Accurate Books and Records;
- Conflict of Interest;
- Contracts/Agreements;
- Fraud, Waste, Abuse, misconduct and mismanagement;
- Member Privacy, Confidentiality, and Security;
- Quality; and,
- Regulatory/Policy.

Further, the CountyCare Compliance Program aims to continually evaluate and strengthen its working communication strategy to increase the CountyCare workforce awareness, including vendors and subcontractors, of the following topics:

- Code of Ethics;
- Privacy, Confidentiality, and Security;
- Accessibility of the Compliance Officer and the compliance team;
- Availability to report issues anonymously through multiple methods;
- Responsibility to report potential and actual issues;
- Consequences of not reporting; and,
- Non-retaliation protections.

The CountyCare Compliance Program scope of work is subject to ongoing review and revision as deemed necessary to ensure ongoing compliance, especially in light of significant staffing challenges. It is designed to accommodate future changes in regulations and laws and may be updated to address issues not currently covered, issues related to new service offerings, or regulatory requirements.

IV. Continued COVID-19 Related CountyCare Compliance Activity

As the COVID-19 pandemic continued through its second year, CountyCare Compliance continued supporting CountyCare operations and membership to address the lingering impacts of the pandemic. Notably, CCH Compliance was tasked with serving as a resource for CountyCare to monitor, interpret, and provide guidance on the rapidly changing regulatory landscape, particularly as related to updates communicated from state and federal agencies and departments. Specifically, CCH and CountyCare Compliance continued to monitor regulatory status of paused programs during the Public Health Emergency ("PHE") and helped provide support as programs started to resume.

Examples of the types of essential topics addressed by CCH and CountyCare Compliance related to COVID-19 include, but are not limited to:

- Privacy and security concerns related to sharing and communicating member information, internally and with vendors and providers, for COVID-19 care management and care coordination related purposes.
- Partner with provider groups, specifically long-term care facilities, to provide webinars to educate members, CCH, and Cook County Department of Public Health ("CCDPH") Equity and Priority-Based Vaccination Sites in the community.
- Continued communications for members and providers to accurately explain the CountyCare Task Force efforts and helpful COVID-19 related resources.
- Resuming and managing the backlog of routine record requests and other Special Investigation Unit ("SIU") and Program Integrity activities paused during the initial onset of the COVID-19 crisis and the PHE.
- Interpretation and impact of notifications received from state and federal agencies regarding delays in implementation of various programs or initiatives that were set to roll out during CFY 2021.

- Continued assessments of permissibility of providing CountyCare members with helpful resources, including Wellness Kits, monetary incentives, and enhanced plan benefits, during COVID-19 and the PHE.

While the COVID-19 pandemic remediation efforts continue, outreach to CountyCare membership to take appropriate preventative measures during this ongoing pandemic and PHE are encouraged and supported by CCH and CountyCare Compliance in partnership with CountyCare operations. Steps taken related to each of these issues were essential to ensure CountyCare operations continued in line with state and federal regulator expectation. Additionally, the continued impacts of COVID-19 can be seen through much of the work reflected related to each element of the CountyCare Compliance Program, listed in Section V. below. CountyCare Compliance anticipates providing significant ongoing support on COVID-19 related issues well into CFY 2022 due to the rise in variants such as Delta and Omicron.

V. Annual Compliance Program Activity – Performance of the Elements

This section of the report serves to summarize activities performed by CountyCare Compliance in CFY 2021 and demonstrate the effectiveness of the program, using the seven Compliance Program Elements for a comprehensive compliance program as criteria, as outlined in the CMS Managed Care Program Integrity requirements and by contractual provisions in the MCCN Agreement. [2] However, as noted previously in this Annual Report, staffing shortages, among other challenges, has limited CountyCare Compliance's scope during this fiscal year.

Element 1:

An effective compliance program maintains and distributes a written Code of Ethics, as well as written policies and procedures, that promote the health plan's commitment to compliance with all applicable requirements and standards related to program integrity and that address specific areas of potential fraud, waste, abuse, mismanagement or misconduct.

The CCH Code of Ethics applies to all CountyCare personnel and includes but is not limited to, volunteers, independent contractors, consultants, business partners, providers, agents and subcontractors. The Code of Ethics, as well as CCH's policies and procedures, support CountyCare's commitment to comply with all federal and state standards, including but not limited to, applicable statutes, regulations and sub-regulatory guidance and contractual requirements. CountyCare also maintains a Compliance Plan demonstrating its commitment to promoting ethical and lawful conduct consistent with all applicable laws, regulations, and contractual requirements, as well as CCH policies, procedures, and Code of Ethics/Standards of Conduct.

[2] See 42 C.F.R. §438.608 and Section 5.35 of the MCCN Agreement (2018-24-201), as amended by KA2 and KA5 in 2020.

Policies and Procedures

CountyCare Compliance, in collaboration with CCH Compliance, engaged in the following activities impacting written guidance to promote and maintain an effective compliance program for CountyCare:

- Reviewed and revised the CountyCare Compliance Plan and multiple CCH Compliance and CountyCare health plan policies and procedures to ensure alignment with changes made to CountyCare's contractual and legal requirements, as well as best practices.
- Developed additional CountyCare Compliance internal policies and procedures related to processes for reporting FWA to HFS OIG.
- Partnered with the Delegated Vendor Oversight team and conducted annual audit of CountyCare's delegated vendors to ensure adherence to CountyCare's policies and procedures and MCCN requirements related to Program Integrity.
- Reviewed, revised, and continued to abide by the CountyCare Compliance Plan specifically outlining compliance responsibilities of the Health Plan and program design, as well as specific CountyCare Compliance policies for high-risk areas focused on Health Plan operations.
- Ensured CountyCare personnel, providers, agents and subcontractors had access to compliance documentation electronically and were provided with hard copies of compliance policies and procedures, upon request.
- Reviewed and/or drafted appropriate compliance contract language for new or updated CountyCare contracts with delegated vendors and providers.

Ad Hoc Activities/Guidance

CountyCare Compliance, in collaboration with CCH Compliance, worked with CountyCare leadership and operational areas to assess compliance with policies, procedures and/or regulatory requirements and, in certain instances, assisted in the development of new policies, procedures and guidance.

Examples of areas assessed:

- <u>Interoperability and Patient Access</u>
  Collaborated with CountyCare Project Management Office ("PMO"), leadership, and operations to review requirements of Interoperability and Patient Access final rule and provided guidance related to member authorization and access requirements throughout the implementation process.

- <u>Contract Review</u>
  Provider Contracting and CountyCare Compliance created a process to ensure appropriate FWA checks were performed for potential Network Providers. By integrating compliance within the contracting process, it ensures continued

confidence in the quality and regulatory compliance of Network Providers who newly contract with CountyCare.

- RFP Engagement
  To ensure proactive compliance by design measures, CCH Compliance developed a comprehensive listing of compliance responsibilities related to its Medicaid line of business for inclusion in relevant RFPs and became a voting member during multiple RFP processes to ensure its scoring of prospective business partners would be a strong consideration by the business.

- Audit Protocol Enhancement
  CountyCare Compliance reviewed annual certification requirements of its vendors and subcontractors and identified opportunities to become more proactive in its review and audit. In CFY 2021 CountyCare Compliance partnered closely with the Delegated Vendor Oversight team during their operational audits and included compliance scoring.

- Recipient Restriction (Lock In) Program ("RRP")
  Continued to provide guidance and reviewed revisions to policies and procedures addressing RRP processes, including how members are enrolled in the Proactive and Reactive Lock-In Programs, communications made to members/providers regarding lock in changes and the process for monitoring program progress to CountyCare Pharmacy and Quality departments.

- Documentation Standards for Health Records Policy
  Collaborated with SIUs to establish and publish requirements related to provider signature requirements, cloning occurrences in medical records, and extender billing.

- Provider Readmissions Policy
  CountyCare Compliance collaborated with CountyCare Clinical Operations to help develop and review a policy related to the identification of member acute care readmissions to ensure compliance with HFS regulations and directives.

- Flexible Housing Pool Benefit
  CountyCare Compliance, the Privacy Officer, Cook County Health, Director of Clinical Services, CountyCare and other CountyCare clinical staff continued collaboration to structure and implement a flexible housing pool benefit for CountyCare members, including how to properly share information across vendors

and partners taking consideration current privacy related contract constraints and minimum necessary requirements.

- MoreCare Medicare Guidance
  CCH, through its Health Plan Services department, continues to partner with MoreCare to operate a Medicare product. CCH and CountyCare Compliance continues to collaborate with MoreCare Compliance to provide guidance to staff working on both the Medicaid and Medicare businesses regarding the differences in Medicare and Medicaid program requirements and the continued need to segregate CountyCare data from MoreCare data and utilize access controls to maintain appropriate protection of data.

- Introduction of a Medicare-Medicaid Alignment Initiative ("MMAI") Health Plan
  Closely partnered with Health Plan Services department, specifically the Project Management Office, to identify and address compliance related responsibilities for the application to launch an MMAI plan offering in CFY 2023.

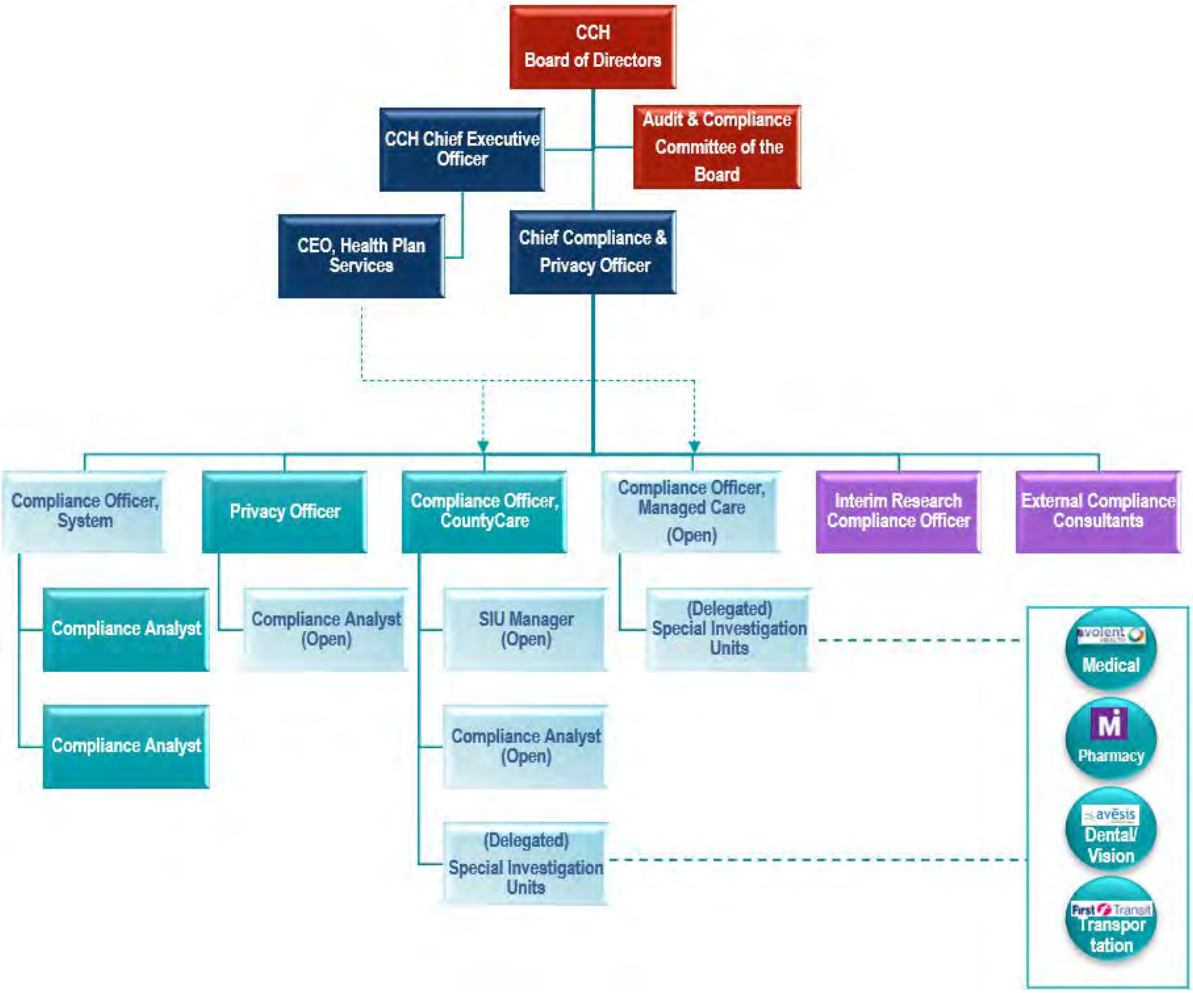
- System Access Tracker
  Continued process for biannual monitoring of system access separate and distinct from CCH systems access as the CountyCare workforce accesses multiple external resources that contains sensitive information including member protected health information, by example through Third Party Administrators ("TPAs").

Element 2

An effective compliance program is led by a Chief Compliance Officer, who reports directly to the organization's Chief Executive Officer and the Board of Directors, responsible for developing and implementing policies and procedures designed to ensure compliance with program integrity requirements. Oversight for the compliance program should be performed by Board and executive-level committees, consisting of members of the Board of Directors and senior management charged with the responsibility of operating and monitoring the compliance program.

Compliance Office and Oversight Committees

Nicole Almiro, the new Chief Compliance & Privacy Officer, onboarded at the end of September 2021, reports to both the CCH Audit & Compliance Committee of the Board and the CCH Chief Executive Officer. In turn, the CCH Audit & Compliance Committee of the Board and the CCH Chief Executive Officer each report to the CCH Board of Directors. The graphic below illustrates the communication and reporting structure for the CountyCare Compliance program, which is embedded within CCH Compliance.



In CFY2021 the Compliance Officer, CountyCare position remained largely open until the end of September 2021 when John Tao joined as Compliance Officer, CountyCare. The past recent Chief Compliance & Privacy Officer, Cathy Bodnar, assumed the primary operational responsibility for CountyCare Compliance in the capacity of interim Compliance Officer, CountyCare until the new Compliance Officer, CountyCare was hired.

For CFY 2021, the primary duties of the Compliance Officer, CountyCare continued to include the following:

- Governance of the Health Plan's Fraud, Waste, Abuse, Mismanagement and Misconduct Program (collectively, "FWA") and Special Investigations Units ("SIUs") to ensure Program Integrity efforts are actively administered.
- High level oversight of the Health Plan's complaint, grievance, appeals and the fair hearing processes for program compliance, including review of trends and patterns through reports and data analysis.

- Ensures Program Integrity issues are reported in accordance with federal, state and local requirements, as well as the guidelines in the Medicaid Managed Care regulations at 42 CFR §438.608 and the CCH MCCN Agreement with HFS.
- Implements and coordinates communication channels to encourage workforce, employees and independent contractors to report issues related to non-compliance and potential Program Integrity issues without fear of retaliation.
- Reviews CountyCare agreements, contracts, addenda, and other relevant documents, as needed.
- Aligns with operational management of CountyCare's sanction/exclusion check to ensure that providers, management, workforce and independent contractors are screened against applicable Federal and state sanction and exclusion lists, where and when necessary.
- Coordinates potential Program Integrity investigations/referrals with the SIU, where applicable.
- Partners with other health plans, HFS, HFS OIG, Medicaid Fraud Control Units ("MCFU"), commercial payers, and other organizations, where appropriate, when a potential FWA issue is discovered involving multiple parties.
- Collaborates with leadership to facilitate operational ownership of compliance.
- Synchronizes system-wide compliance program materials and messaging to present a uniform approach consistent with CCH Compliance.
- Oversees, directs, delivers, tracks, or ensures delivery of compliance training, both global and specialty, for employees, Network Providers, vendors, and consultants.
- Develops, assesses, evaluates, implements, maintains, and updates compliance policies and procedures to ensure adherence with relevant requirements.
- Establishes a structured process for regulatory review, monitoring, and dissemination of information.
- Modifies policies, procedures, and projects to reflect changes in laws and regulations.
- Develops and coordinates compliance projects with CCH system entities and performs prospective reviews in conjunction other personnel as deemed necessary.
- Ensures Compliance Program reports are produced for the Chief Compliance and Privacy Officer, Chief Executive Officer, Board of Directors, and Audit and Compliance Committee of the Board of Directors.
- Ensures regular reports are produced for the State of Illinois, and all other applicable state and federal governmental entities, as required and requested.

The following committees are tasked with oversight over the CountyCare Compliance Program, as outlined below:

- **Audit & Compliance Committee of the Board** meets quarterly and advises the CCH Board of Directors regarding the implementation of standards and

processes to assure professional responsibility and honest behavior, compliance with regulatory requirements, and risk management. The Audit & Compliance Committee of the Board receives periodic updates regarding the CountyCare Compliance program, including FWA metrics and assessments of risk areas.

- **Regulatory Compliance Committee**, chaired by the Compliance Officer, CountyCare, meets quarterly and provides oversight of and guidance to CountyCare operations to ensure regulatory compliance and fulfill Compliance Program requirements, which include the implementation and operation of the Compliance Program. The Regulatory Compliance Committee also reviews CountyCare activity pursuant to Compliance Program requirements and contractual requirements, including, but not limited to audits, monitoring activity, and corrective action plans. The Regulatory Compliance Committee reports through the Chief Compliance and Privacy Officer to the Audit & Compliance Committee of the Board.

Additionally, the Compliance Officer, CountyCare participates in the following regular meetings, committees and/or Program Integrity related meetings to fulfill their responsibilities as a senior executive within Health Plan operations:

- **CountyCare Senior Leadership,** a weekly meeting with CountyCare Senior Leadership which rotates topics on a weekly basis focusing on areas such as: Plan Metrics, Project Management Office initiatives and status, Finance Roadmap/MCAP, Strategic Domains such as Staff & Membership Experience/Quality/Health Equity. This weekly meeting is comprised only of CountyCare senior leadership and reviews the health of the Health Plan across all metrics.

- **HFS OIG MCO Subcommittee,** comprised of HFS OIG and Managed Care Organization's ("MCO") compliance members involved in the program integrity functions of their respective MCOs. This subcommittee meets monthly to review and share information regarding FWA activity as it relates to specific providers and trends.

- **Program Integrity Meetings,** comprised of delegated vendors occurring on a bi-weekly or monthly cadence, depending on the vendor and amount of activity. Led by the Compliance Officer, CountyCare, and attended by other members of CCH Compliance, as needed, the meetings provide an overview of the vendors' activities and serve as a forum to review, approve, modify, or reject the direction of audits, investigations, data mining efforts and recoupment activity.

- **Grievance and Appeals Committee,** a subcommittee of the CountyCare Quality Improvement Committee ("QIC") responsible for maintaining compliance with contractual, federal, and accrediting body requirements, including NCQA standards, related to the processing of grievance and appeals. The scope of the committee includes tracking and analysis of member grievances and appeals from

all delegated vendors including type and timeliness of resolution, performing barrier and root cause analysis, and making recommendations regarding corrective actions as indicated.

- **Delegated Vendor Oversight Committee** meets quarterly to provide oversight of the operations affecting the scope of functions of delegated vendors and subcontractors to ensure compliance with statutory and contractual requirements. The committee provides oversight of quarterly delegation audits, monthly joint operations meetings and regular monitoring of member and provider complaints. Identified areas of compliance risk are referred to CCH Compliance and/or CountyCare Compliance for assessment, when appropriate.

- **Pharmacy and Therapeutics Committee** meets quarterly to provide oversight of the pharmacuetical and therapeutic operations to ensure compliance with statutory, contractual, and regulatory requirements such as the member Recipient Restriction Program. The committee also provides oversight of pharmaceutical and therapeutic policies, procedures, and operational procfesses.

Element 3

An effective compliance program should institute and maintain regular, effective education and training programs for all affected employees, including the Compliance Officer, Board of Directors, senior managers, and health plan employees, regarding the importance of complying with federal and state compliance related requirements.

Education and Training

Traditional CountyCare Compliance related training opportunities were limited in CFY 2021 due to staff constraints and the lingering impacts of COVID-19. However, CountyCare Compliance was able to participate in the following opportunities to present training related to compliance, FWA and HIPAA.

1. CountyCare – Provider FWA training and New Employee/Contractor Orientation
    - Reviewed and updated provider Fraud, Waste and Abuse training to provide new content related to Program Integrity contract changes.
    - Participated in New Employee training, providing new hires (both permanent and contractual) an introduction to all aspects of CountyCare, with dedicated time for compliance program introduction and privacy guidance.
2. CountyCare – HIPAA Training and Guidance for Care Management Staff
    CountyCare Compliance, in conjunction with the CCH Privacy Officer, created an extensive Privacy training for CountyCare Care Coordinators at the request of CountyCare leadership. Training materials were developed over several months and included regular check-in calls with care coordinators to ensure key areas of concern were addressed. The final training deck was delivered to CountyCare Care Coordination in late CFY21. In early CFY22, Privacy will

work with the Care Coordinators on a "train the trainer" arrangement to deliver this training to new Care Coordinators.

3. Targeted Education
   Continued to provide guidance and commentary regarding updates to 42 CFR Part 2 related to the disclosure of substance/alcohol abuse records.

Element 4

An effective compliance program should maintain several lines of communication to receive complaints from employees, subcontractors, network providers, members and the HFS OIG, including the adoption of procedures to protect the anonymity of complainants (such as the use of a hotline) and to protect whistleblowers from retaliation. Issues reported via communication channels should be tracked, investigated, and reported (as needed).

Receiving and Responding to CountyCare Related Complaints

1. Several lines of communication are available for reporting issues and complaints related to CountyCare. Specifically, CountyCare Compliance:
   - Maintained an e-mail address for CountyCare Compliance communications (countycarecompliance@cookcountyhhs.org)
   - Monitored Third Party Administrator's ("TPA") support and assistance to CountyCare members through the TPA's hotline service. Met bi-weekly with TPA's compliance staff to discuss issues received through the hot line and appropriate responses to those issues.
   - Shared the accessibility of reporting concerns to the CountyCare workforce through:
     - A hotline service by a third party to preserve anonymity if desired;
     - A separate toll-free number for privacy breaches; and
     - Open door policies for CCH Compliance leadership and each team member.
   - Established relationships and engaged internal and external resources to assist with investigations.
   - Identified trends and patterns to mitigate organizational risks and facilitate operational improvement.
   - Presented trends and patterns to the Regulatory Compliance Committee, CountyCare Senior Leadership meetings, Audit & Compliance Committee of the Board, and the Managed Care Committee of the Board, as appropriate.

2. There are established CountyCare Compliance processes for responding to issues and complaints received. CountyCare Compliance maintains processes for issue, complaint management, and resolution as follows**:**
   - The workflow process for compliance contacts follows SBAR, an acronym for **S**ituation, **B**ackground, **A**ssessment, and **R**ecommendation.
   - Initially, CCH Compliance is made aware of a **S**ituation,

    - Contact is made through one or multiple methods e.g., via direct phone call or call through the compliance hotline, e-mail, and/or in-person contact;
    - An inquiry is made, or a concern is described;
    - An individual(s), area(s) or situation is identified.
- This **B**ackground information is categorized, compiled, and logged in the CCH Compliance tracking tool.
- An **A**ssessment occurs,
    - Reviewed and followed contractual obligations, organizational policy, federal, state, and county regulations related to the incident to evaluate the situation presented;
    - Determine what the problem is and/or the severity.
- Lastly, the **R**ecommendation,
    - Establish a pathway for mitigation and remediation. These may include further auditing of documentation, mitigating harm, and potentially informing the appropriate government entity.
    - This always involves engaging and collaborating with leadership and appropriate entities.
    - Share recommendations with the reporter, as appropriate.

3. Categories have been defined to allow CountyCare Compliance to accurately organize and report compliance inquiries/issues received. The inclusion of an item in a specific category does not substantiate the issue; rather it classifies the issue within a defined category. The CFY 2021 CountyCare Compliance issues addressed fall within the following categories:

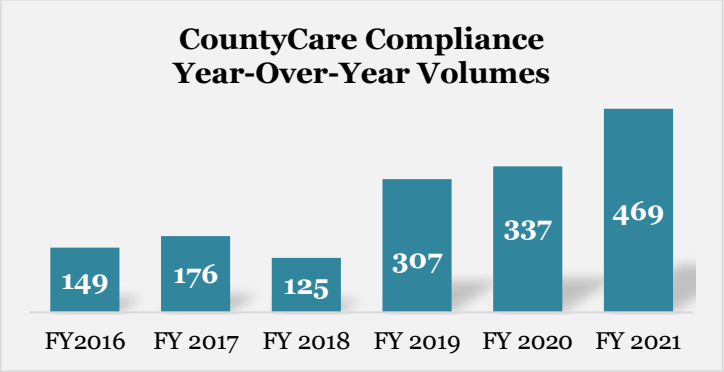
    - Contractual Issues & Reviews;
    - Regulatory/Policy Matters;
    - HIPAA Privacy, Confidentiality and Security;
    - Accurate Books & Records;
    - Fraud, Waste and Abuse;
    - Quality/Patient Safety
    - Conflict of Interest; and
    - Other (e.g., subpoenas, unique grievance & appeals guidance, involuntary discharge of CountyCare member, etc.).

CFY 2021 CountyCare Compliance Contact Volume

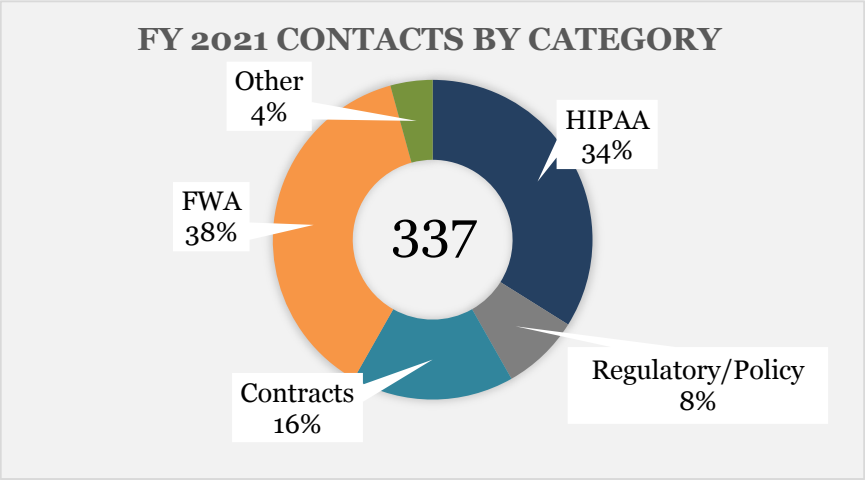
1. Total Volume of General Compliance Contacts

469 contacts were documented for the CountyCare Compliance Program. The chart that follows illustrates the year-over-year activity, which shows a significant increase of nearly 33% compared to the previous fiscal year. There are several factors which may be attributed to this increase. First, this increase is a result of the continued success of CountyCare, the increasing membership, and variety of new initiatives, including the potential introduction of an MMAI line of business to the Health Plan Services business. Secondly, as CountyCare

becomes a more recognized brand, malfeasance, bad actors, and actions are expected to increase requiring compliance to be more involved in proactively monitoring FWA trends and patterns. Finally, CountyCare Compliance and CCH Compliance currently support subpoena and subrogation requests. Such requests are not a standard compliance function but have seen increasing demand year over year. This year there was a 38% increase in the total number of subpoena and subrogation requests (from 66 to 97). In 2022 compliance will be transitioning these requests to the CountyCare operational team.



2. Inquiry/Issue Breakdown by Category CFY 2021 (December 1, 2020-November 30, 2021)



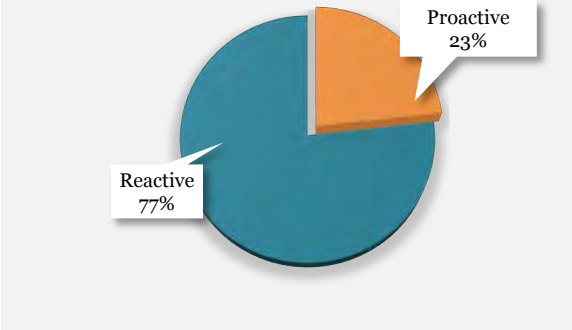
The chart above illustrates the volume of CFY 2021 contacts received by CountyCare Compliance, separated out by issue category. The associated category count follows,

Categories	Count	Categories	Count
HIPAA - Privacy, Confidentiality and Security	159	Contracts/ Agreements	77
Fraud, Waste, Abuse	176	Other	20
Regulatory/Policy	37		

Issue types included in the "Other" category include queries regarding: documentation, conflict of interest, quality/member safety, human resources, and others, as applicable.

3. CFY 2021 Proactive vs. Reactive

Of the 469 CountyCare contacts in CFY 2021, 23% or 109 contacts, were proactive while 77% or 360 contacts were reactive.



Proactive contact is optimal because individuals seek guidance prior to the occurrence of an event or activity rather than retrospectively.

CountyCare Compliance continues to look forward to increasing awareness of CountyCare Compliance so issues may be addressed more proactively in the coming year, where appropriate resources are available.

4. Privacy, Confidentiality and Security ("HIPAA")

As a covered entity and business associate of HFS, CountyCare is required to safeguard privacy for plan members. Privacy and security of member information is highly regulated, and this category accounted for 159, or 34% of all CountyCare issues in CFY 2021. As noted in the CCH Compliance Annual Report, CountyCare Privacy is exclusively managed by the Privacy Officer with support provided by CCH Compliance Analysts and external compliance consultants from Strategic Management, LLC.

During CFY 2021, 24 privacy related incidents and breaches were reported to CountyCare Compliance. Incidents occur when, after a risk assessment, it is determined that the event does not rise to the level of a HIPAA breach. A total of seven privacy related contacts rose to the level of a reportable HIPAA breach, which required notification to members. Of the seven breaches, five occurred in relation to activities performed by CountyCare business associates while the remaining two involved CountyCare employees. All employees involved in these breaches, both CountyCare and business associates, were provided additional training as part of mitigation efforts.

The two CountyCare reported breaches involved misdirected communications sent to the wrong individual (for example, mailing a prior authorization letter to an incorrect member or leaving a telephone message for an individual who was not the intended recipient). In both cases, the Privacy Officer notified the affected member and ensured compliance with all regulatory requirements.

Of the breaches caused by CountyCare business associates, two were caused by Evolent due to "bugs" found during system upgrades. One involved an impermissible disclosure of 43 CountyCare members' Protected Health Information ("PHI") to other members through Evolent's Member Portal. The Privacy Officer notified the 43 affected members, along with HFS.

The second instance of an Evolent Member Portal breach was reported to CountyCare by a member. Compliance investigated and collaborated with Evolent to resolve the issue and provide regulatorily required notifications. This breach affected sixty members.

The most significant breach in CFY 2021 involved an impermissible disclosure of 898 CountyCare members' PHI when First Transit, a CountyCare benefit administrator providing non-emergency medical transportation, subcontracted transportation providers not registered with First Transit prior to providing CountyCare members service. As unregistered providers the CountyCare member PHI access these drivers had was impermissible. The Chief Compliance & Privacy Officer and Privacy Officer enforced the contract between Cook County Health and First Transit, requiring First Transit take corrective actions including: terminating their subcontract, notifying affected members, notifying the media, and posting necessary substitute notices.

Additionally, 97 of the contacts included within the HIPAA category reflect activities related to reviewing and processing record requests for CountyCare member records as related to subpoenas and subrogation. These contracts were exclusively managed by CCH Compliance due to CountyCare Compliance staffing shortages through CFY 2020 and a majority of CFY 2021.

Finally, 31 contacts within the HIPAA category reflected guidance or review activities provided by the Privacy Officer and external compliance consultants from Strategic Management, LLC to confirm permissible instances of access, use or disclosure of member protected health information by organizational staff and benefit administrator/vendor partners.

5. Fraud, Waste, and Abuse, Mismanagement and Misconduct (collectively, "FWA")

A significant amount of time and effort are assigned to the prevention, detection and elimination of FWA by CountyCare Compliance. Of the 469 CountyCare contacts in CFY 2021, 38% or 176 contacts, were related to FWA. More information regarding CountyCare's efforts related to these contacts can be found under Element 6 below, as the majority of these contacts were identified during or resulted in auditing, monitoring or investigation related activities.

Receiving and Responding to Communications from HFS OIG

CountyCare Compliance is contractually obligated to receive and respond to communications received from HFS OIG, both on a regular basis (e.g., monthly), as well as an ad hoc basis.

Types of communications received from HFS OIG include several types of Provider Alerts, which impact the various types of providers used to provide benefits and services to CountyCare members, including Providers, (Medical, Dental and Vision), Pharmacies, Durable Medical Equipment ("DME"), Skilled Nursing Facilities ("SNFs"), Homemakers and Transportation providers.

Below is a summary of the volume of Provider Alerts, separated by notice type, received in CFY 2021 from HFS OIG, which CountyCare Compliance then communicated to its relevant SIUs and benefit administrators, as appropriate:

CFY 2021 Provider Alerts	
Active Investigation (also known as "Deconfliction")	12
Payment Withhold	10
Payment Suspension Release	5
Disenrollment, Termination and Voluntary Withdrawal	65
Reinstatement	9
TOTAL	**101**

Additionally, HFS OIG communicates official data requests for information on an ad hoc basis, requiring CountyCare Compliance to collaborate with its SIUs, depending on the type of provider that is the focus of the request, to obtain and submit claims data, provider contracts, provider investigation or audit information, or communications made to a specific provider. During CFY 2021, CountyCare received and responded to **46** requests for information submitted by HFS OIG.

Element 5

An effective compliance program maintains a system to respond to allegations of improper/illegal activities and coordinates with relevant departments to ensure enforcement of appropriate disciplinary action, using well-publicized disciplinary guidelines, against workforce members who have violated internal compliance policies, program integrity related requirements, applicable statutes, regulations or Federal health care program requirements.

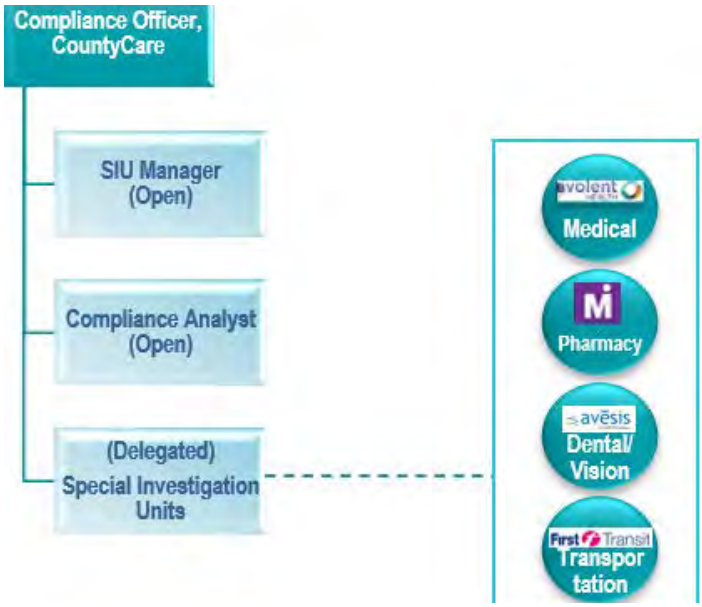
Enforcing Standards

During CFY 2021, CountyCare Compliance exercised and broadened the scope of its enforcement standards through:

- **Investigations and Guidance for Employee Related Corrective Actions.** CountyCare Compliance, via CCH Compliance, investigated employee related complaints (for example, those related to confidentiality complaints or conflict of interest) and provided guidance to involved employees and leadership to remediate the situations and avoid repetition of the incident.

- **Monitoring Corrective Action Plans ("CAPs"), Deficiency Action Plan ("DAPs"), and Performance Improvement Plans ("PIPs").** CountyCare Compliance, in collaboration with the CountyCare Delegated Vendor Oversight program, monitors any CountyCare vendor placed on a CAP, DAP or PIP for issues related to program integrity or compliance. During CFY 2021, CCH Compliance monitored one (1) vendor for improvement based on two (2) compliance related CAPs, DAPs or PIPs.

- **Privacy and Security ("HIPAA") Breach Assessments.** The Privacy Officer maintains consistency in approach for breach assessments and to provide guidance to CountyCare workforce members and business associates.



- **Fraud, Waste, Abuse, Mismanagement and Misconduct (collectively, "FWA") Monitoring.** CountyCare Compliance collaborated closely with the Special Investigation Units ("SIUs") of Delegated Vendors to identify potential FWA. CountyCare continues to work with its SIUs to perform data analytics, including DRG auditing and coding analysis, to identify, investigate and report unusual behaviors by providers, which includes processes for reaching out to providers to educate on issues identified as well as suggesting network termination for non-compliance with network provider agreement provisions, where appropriate.

- **Partnerships with Governmental Agencies.** CountyCare Compliance partnered with the HFS, HFS OIG, and Illinois' Medicaid Fraud Control Unit ("MFCU").

- **Partnerships with non-Governmental Agencies**. CountyCare Compliance continues to collaborate with a number of organizations related to the detection of fraud and wrongdoing in the insurance industry. These non-governmental organizations include other managed care organizations and health plans, the HealthCare Fraud Prevention Partnership ("HFPP"), National Insurance Crime Bureau ("NICB"), Midwest Anti-Fraud Insurance Association ("MAIA"), and the professional organization of compliance professionals, Health Care Compliance Association ("HCCA").

Element 6

An effective compliance program utilizes risk assessments, audits and/or other evaluation techniques to monitor program integrity and assist in the prevention and/or reduction of identified problem areas related to fraud, waste, abuse, mismanagement and misconduct.

CountyCare Delegated Special Investigation Units

Prevention, detection and elimination of fraud, waste, abuse, mismanagement and misconduct (collectively, "FWA") is a central responsibility for CountyCare Compliance. Benefit and Program Integrity is critical not only because it is a contractual requirement and a significant focus by the State and Federal government but because it is *the right thing to do*. The impetus of this key initiative is to ensure federal, state, and county taxpayer dollars are spent appropriately on delivering quality, medically necessary care and preventing FWA in addition to protecting CountyCare members and providers.

To identify potential FWA, CountyCare Compliance partners with each delegated vendor through their dedicated areas commonly known as Special Investigation Units ("SIU").

As reflected in the adjacent organization chart, the Compliance Officer, CountyCare provides direct oversight of program integrity activity. CountyCare Compliance is actively pursuing an "SIU Manager" role within the organization to provide additional support and alleviate spend on external consultant partners moving forward in CFY 2022.

Auditing and Monitoring Efforts for SFY 2021

Fraud, Waste, Abuse, Mismanagement and Misconduct (collectively, "FWA")

CountyCare Compliance relies upon the monitoring, auditing, investigation, and utilization controls performed by the designated SIUs carried out by its delegated vendors. FWA activity matters are raised through multiple lines of communication, either to each delegated vendor or directly to CCH Compliance. All allegations are tracked and monitored to resolution. In addition, other auditing and investigation measures are undertaken through the SIUs.

CountyCare continues to utilize data mining, a proprietary catalogue of concepts developed by its SIUs, to analyze CountyCare claims and identify providers with unusual billing patterns and reviews. CountyCare Compliance also investigates tips received from HFS, HFS OIG, other Managed Care Organizations ("MCOs"), healthcare fraud groups, CountyCare employees, the media, and other sources to identify FWA.

All Program Integrity activity is tracked by State Fiscal Year ("SFY") for state reporting purposes and not by County Fiscal Year ("CFY"). The SFY runs from July 1st through June 30th of each year.

Metrics for both SFY 2021 along with the first quarter of SFY 2022, as reported to HFS OIG on a quarterly basis, follow:

S-FY	Reporting Period	Tips[3]	Referrals to HFS OIG[4]	Overpayments Identified[5]	Overpayments Collected[6]
2021	Q1 07/01 -09/30/20	49	0	$ 1,277,500	$ 196,600
2021	Q2 10/01 – 12/31/20	106	8	$ 1,697,500	$ 304,000
2021	Q3 01/01 – 03/31/21	49	20	$ 1,970,360	$ 713,020
2021	Q4 04/01 – 06/30/21	46	9	$ 1,378,755	$ 485,839

S-FY	Reporting Period	Tips	Referrals to HFS OIG	Overpayments Identified	Overpayments Collected
2022	Q1 07/01 – 09/30/21	100	18	$ 583,637	$ 66,066

The results of the annual Program Integrity activities are reflected in the metrics above with a total of $1,699,412.03 collected in overpayments in SFY 2021. The amount recovered in SFY 2021 was a 104% decrease over the $5,396,934.89 recovered in SFY 2020. There are several reasons for the decrease.

First, the SFY 2021 recovery amount exceeded normal recovery amounts by nearly 170% and should not set the standard for recoveries on a year over year basis. The unique increase in SFY 2021 was driven in part due to the initial approval from HFS OIG to begin recoupment of monies temporarily suspended during the PHE. As discussed previously in this Annual Report, the PHE resulted in a backlog of recoveries due to HFS OIG temporarily suspending recoveries. As the

[3] The term *tip*, as defined by HFS OIG, includes any allegations or incidents of suspected FWA opened on a CountyCare provider by the health plan. Often, tips reported to HFS OIG on a monthly basis are not fully vetted referrals, only preliminary information that SIUs are providing to HFS OIG in real time. Additionally, not all investigative activity is reported to HFS OIG via the Tips report (for example, data mining efforts or audits based on proprietary algorithms are not reported.)

[4] Where CountyCare Compliance identifies actual instances of FWA, mismanagement, or misconduct, information regarding the investigation is also *referred* to HFS OIG.

[5] *Overpayments Identified* indicates the dollar amount identified for possible overpayment (for example, the total amount paid to the provider for the identified inaccurate codes) during the quarter, based the investigation or audit conducted by the SIU. These amounts may be supported through additional review of documentation submitted by the provider or may be offset if a provider elects to bill a corrected claim.

[6] *Overpayments Collected* represents the dollar amount recovered from the provider/group, as allowable by the MCCN Agreement.

impacts of the PHE decline and a new normal stabilizes a decrease in recoveries from the backlog would be expected.

Second, with revisions to the MCCN Agreement made by the KA2 amendment, new processes were implemented between the State of Illinois and all Managed Care Organizations within the Medicaid program, including CountyCare. HFS OIG now requires all requests for recoupment receive prior approval which has added additional time in the already lengthy recoupment processes. Additionally, due to HFS OIG reporting changes, the numbers reported no longer include recoveries not requiring traditional audit or investigation. Specifically, recoveries related to administrative errors, including data mined activities, are no longer reported to HFS OIG. However, data mining recoveries for Q1 SFY 2022 (July – September 2021) are included in the table above for purposes of this Annual Report. Data mining activities continue to be a significant tool used by CountyCare Compliance to combat FWA.

Third, due to the timing of claim audits and recoveries the PHE continues to have an impact on claim recoupments. Notably, a backlog of approximately 22,500 claims identified using clinical audits at the DRG level during the temporary PHE suspension received HFS OIG approval for recovery within the past year. The volume of claims has led to a sizable backlog requiring a significant amount of recovery effort. These claims total approximately $8.3M CountyCare may expect to recover during 2022. To date, $150K has been recovered of the total projected amount.

CountyCare Compliance continuously monitors the process to ensure appropriate action is taken, including reporting of suspected FWA to HFS OIG. In SFY 2021, CountyCare referred 37-cases to the HFS OIG for possible FWA – an increase of 136%. 18 referrals have been made in Q1 2022 alone, highlighting the increased oversight of CountyCare providers.

- Annual Compliance Audit and Attestation

  CountyCare Compliance continued to utilize an Annual Compliance Attestation, issued to all CountyCare's delegated vendors in June 2021. The Compliance Attestation required all vendors to attest to several compliance provisions in their contracts, compliance with the requirements of Section 9.2 of the MCCN. Additionally, each of CountyCare's delegated vendors completed a compliance audit during CFY2021, which was facilitated through partnership with the Delegated Vendor Oversight audit process.

- Grievances and Appeals Activities

  CountyCare Compliance continues to provide high-level oversight related to grievance and appeals activities at the plan level. As needed, guidance and assistance is provided related particularly to contractual and regulatory timeframes. Additionally, CountyCare Compliance

participates in the quarterly CountyCare Grievance and Appeals Committee, as well as Delegated Vendor Oversight meetings.

Regulator Audit Activity for CFY 2021

CountyCare Compliance held several meetings with new HFS OIG Inspector General Brian Dunn, when he first started his role in early 2021. No official compliance related audit requests were issued by HFS OIG and HSAG during CFY 2021.

Risk Assessment

The primary focus within CountyCare Compliance is prevention, detection and elimination of FWA, in addition to other areas of risk identified in CFY 2021. Risk assessment currently is an ongoing exercise within CountyCare Compliance, performed on a consistent basis by monitoring issues that arise via the various lines of communications offered by the Department as well as in day-to-day communications with CountyCare operations and benefit administrators.

Where resources are available in CFY 2022, CountyCare Compliance will build on the 2021 effectiveness review conducted by Strategic Management Services, LLC and initiate an annual risk assessment with executive leadership and key thought leaders nationally to identify outstanding risks and challenges to meeting the standards of an effective health plan compliance program.

Element 7

The Effective compliance programs maintain processes for the investigation and remediation of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals. Additionally, processes are in place to ensure that prompt reporting of all overpayments identified or recovered to HFS OIG.

Identification of Systemic Issues

Sanction Screening Checks

- CCH maintains a policy and procedure paralleling requirements set forth by the MCCN Agreement and the Department of Health and Human Services, Office of Inspector General, to ensure screening of all contractors and workforce members.
- The goal of the policy is to avoid employing, engaging, contracting or agreeing with any individual or entity excluded or "sanctioned" from participation in a federal health care program or who is debarred from participation in federal procurement or non-procurement programs for the provision of goods or services.
- Sanction screening requirements continue to be embedded within each CountyCare contract and each CountyCare benefit administrator is required to screen each provider in their networks.
- Data is provided on a monthly basis to CountyCare Compliance to verify that sanction screening checks were conducted for medical and behavioral health providers. CountyCare vendors are also required to attest, on an annual basis, sanction screening checks are performed in line with their contract requirements.

Prompt Reporting of Program Integrity Data to HFS OIG

CountyCare Compliance is contractually obligated to submit both monthly and quarterly reports to HFS OIG capturing its Program Integrity activities, particularly with respect to FWA identified that is related to providers/groups enrolled in the HealthChoice Illinois Medicaid program.

- Monthly Tips Report.
  On a monthly basis, CountyCare Compliance submits a Tips Report to HFS OIG, documented within an Excel document, which lists out any allegations or incidents of suspected FWA that has been opened by the health plan related to a provider within that past month which impacts the HealthChoice Illinois Medicaid program. Tips reported are not designed to be a fully vetted referral to HFS OIG; rather, they are designed to help provide necessary information to HFS OIG and avoid delays that would impact appropriate law enforcement or administrative review/action even before an audit or investigation has fully vetted the allegation.

- Quarterly FWA Report.
  The MCCN Agreement requires CountyCare Compliance to submit a quarterly FWA report to HFS OIG. This report (also known as the "FWA Tool") must include all instances of suspected FWA, among other Program Integrity data requested, or indicate there was no suspected FWA during that quarter. While the FWA Tool is not intended to include administrative billing issues or routine claim errors, a considerable amount of time has been spent clarifying with HFS OIG the types of Program Integrity related information that should be included within the report. Consequences from such discussions have been reflected in the above section "Auditing and Monitoring Efforts for SFY2021". Discussions will continue into 2022, and beyond, with additional changes likely under Inspector General Brian Dunn's leadership.

  CountyCare Compliance devotes a significant amount of time and effort to develop, review and submit reports to HFS OIG, including comprehensive coordination and communication with the various SIUs to gather and validate the required Program Integrity related activity information and data. CountyCare Compliance and resources within CCH Compliance collaborated to develop both an internal policy outlining the parameters for developing, reviewing and submitting the required reports listed above to HFS OIG and will leverage existing Salesforce tools to help consolidate data from all the various SIU partners and streamline the reporting process.

Prompt Responses to HFS OIG Data Requests

HFS OIG and its partner governmental agencies, such as the US DOJ, regularly submit data requests to CountyCare for review and completion. These requests can involve a

variety of asks including, but not limited to, claims reviews of specific providers, documentation used for certain billing practices, or any number of items related to the MCO. In CFY 2021 CountyCare received 46 such requests, averaging almost one a week. There are typically two types of requests.

Request for Information

These typically have a short turnaround time between 48 hours and a few weeks and are centered on information related to specific providers are specific situations. CountyCare must diligently review the request and partner with the appropriate SIU benefit administrator to ensure timely and accurate responses are provided to HFS OIG.

Requests for Audit

Requests for audit are lengthier data requests from HFS OIG and their partner governmental organizations which require CountyCare review the request, partner with the appropriate SIU benefit administrator, and oversee and validate the audit scope and findings. These requests typically have a turnaround time of three to six months and may require varying levels of detail.

VI. Looking Ahead to CFY 2022

In CFY 2022, CCH Compliance will continue to focus on maintaining adherence to contractual requirements and healthcare compliance best practices as the program matures. As CountyCare relies heavily on delegated vendors, monitoring for adherence to CountyCare policies, contractual, and regulatory standards are critical to avoid sanctions and ensure that federal, state, and county taxpayer dollars are spent appropriately on delivering quality, necessary care and preventing FWA in addition to protecting CountyCare members and providers. The Program will continue ongoing activities related to risk reduction in the areas of compliance, policy implementation, and the development and implementation of monitoring and auditing efforts.

These priorities have been established for the CountyCare Compliance Program:

- Continued training and onboarding of the new designated Compliance Officer for CountyCare and increased effort to locate additional resources for CountyCare Compliance to better concentrate on initiatives designed to improve the Compliance Program, Program Integrity, or compliance presence for CountyCare operations as a whole.
- Strengthen CountyCare oversight of FWA Activities:
    - Foster continued partnerships with HFS OIG and the State's MFCU to develop best practices in Corporate Compliance for CountyCare and enhance relationships with non-government organizations and other MCOs' to build a network of skilled investigators and increase effective Program Integrity efforts.
    - Continue efforts to review and approve new concepts for data mining and clinical audit recovery activities.

    - Strengthen the partnership with the transportation delegated vendor to scrutinize potential FWA.
- Conduct a comprehensive annual risk assessment with executive leadership and key thought leaders nationally to identify outstanding risks and challenges to meeting the standards of an effective health plan compliance program.
- Increase workforce education and knowledge regarding the Compliance Department's duties, the compliance hotline, and a workforce member's duty to report.
- Continue developing and maturing collaboration opportunities with CountyCare Delegated Vendor Oversight program to conduct annual compliance related audits of vendors.
- Foster partnerships with other CountyCare departments and delegated vendors to fulfill contractual obligations in Program Integrity and state reporting and encourage proactive identification and discussion of issues with CountyCare Compliance.
- Continue to investigate all issues/complaints brought to the attention of the Program.
- Uphold compliance with continuously changing contractual requirements and industry best practices as CountyCare continues as the largest Medicaid Managed Care Organization in Cook County.
- Serve as a compliance and privacy resource to the workforce and delegated vendors.
- Mature the CountyCare Compliance Program and continue to incorporate best practices to cultivate a culture of compliance throughout the Health Plan.
- Maintain CountyCare Compliance Program recognition locally and nationally.

COOK COUNTY
HEALTH

Cook County Health System Compliance Program

Annual Report
Fiscal Year 2021
December 1, 2020 – November 30, 2021

January 21, 2022

Table of Contents

I. Executive Summary....3
II. Introduction....4
III. Building Blocks – Program Infrastructure and Scope....5
IV. Ongoing COVID-19 PHE Related Activity....7
V. Being Present – Communication – Fostering Transparency....10
VI. Annual Compliance Program Structures - Performance of the Elements....10
- Element 1 - Standards of Conduct, Policies and Procedures....11
- Element 2 - Compliance Office and Oversight Responsibilities....14
- Element 3 - Education and Training....16
- Element 4 - Receiving and Responding to Complaints....17
- Element 5 - Enforcing Standards....23
- Element 6 - Monitoring and Auditing....24
- Element 7 - Prevention....25

VII. Looking Ahead to 2022....26

I. Executive Summary

The Fiscal Year (FY) 2021 Compliance Program Annual Report summarizes the primary compliance activities that the Cook County Health (CCH) System CCH Compliance Program (CCH Compliance Program) accomplished in FY 2021 and identifies priorities for FY 2022.

During this past fiscal year, the CCH Compliance Program achieved many of its stated goals, implemented new initiatives despite several hardships including the effects of the COVID-19 Public Health Emergency (PHE) and reduced staffing levels in the department, and established plans to expand on this progress in FY2022. Notable activities include:

- New Leadership in the Office of Corporate Compliance: Compliance welcomed new Chief Compliance & Privacy Officer, Nicole Almiro, to replace Cathy Bodnar after Cathy announced her retirement in November 2021. Compliance also hired CountyCare Compliance Officer, John Tao.
- Ongoing COVID-19 PHE: Continuing monitoring of the changing regulatory landscape in response to COVID-19, synthesizing numerous, significant regulatory changes and communicating guidance to operational leadership and clinical staff. Collaboration with key departments in rolling out COVID-19 vaccinations to staff, patients, and the general public.
- Expanding Privacy Expertise: Expanded on existing Health Insurance Portability and Accountability Act (HIPAA) privacy expertise and offered progressively more review of issues and guidance on privacy matters falling within other federal regulations, such as 42 CFR Part 2, and state privacy laws.
- Local Government Records Management: Embarking on a revision of the Record Retention Schedule for Cook County Health that addresses current record retention regulatory requirements and assimilates categories for user-friendly reference.
- System-Wide Policy Committee Participation: Continued Compliance presence on the multi-disciplinary team responsible for policy evaluations and approval.
- Accessibility: On an ongoing basis, Compliance continues to respond to inquiries, allegations, and complaints in addition to monitoring these contacts for patterns and trends.
- Consultations: Providing ongoing Compliance review and guidance as a member of several multi-disciplinary task forces and committees.
- Dual Employment Survey: Administering the FY 2021 survey to all CCH employees. This requirement is based on the Cook County Ethics Ordinance and is mandatory through CCH Personnel Rules and the Dual Employment Policy.

In FY 2022, CCH Compliance plans to continue serving as a trusted and reliable resource for all workforce members within CCH, as well as CCH patients, CountyCare members, vendors, and the general public. The department will conduct its own analyses and will collaborate with internal

partners to assess and prioritize risk areas and areas of potential non-compliance and work toward improving those areas.

Notable priorities for FY 2022 include:

- Compliance Education: Given the ever-changing healthcare regulatory environment, there is a need to update and communicate these changes quickly to employees in a manner that is easily understood and retained. To this end, CCH Compliance will develop 5-minute or less animated educational videos designed to shorten the lengthy learning topics to smaller units of learning content to reduce information overload, simplify complex topics, and entertain and engage in an effort to enhance retention of and therefore compliance with the topic.

- Research Compliance Program: Continued development of our Research Compliance Program is fundamental for ensuring compliance with the various laws and regulations from multiple agencies and enforcement bodies, educating employees, revising and establishing processes and procedures, and assisting in preventing future problems. Upcoming area of increased focus is clinical trial billing compliance including how CCH patients may be flagged as participating in a research study within the electronic medical record and whether enhanced bill review processes are needed for charges related to research studies.

- Clinical Documentation Education Program: Centers for Medicare & Medicaid Services (CMS) recently made landmark changes to documentation, coding, and billing for evaluation and management services for outpatient visits while evaluation and management services for inpatient services remain unchanged. To enhance compliance with these recent changes, CCH Compliance will develop a clinical documentation education program to heighten awareness and assist providers and staff with these clinical documentation changes that will improve compliance with coding and third-party billing.

- Implementation of Recommendations for Improvement to CCH Compliance Program: Utilizing the Compliance Program Evaluation Report from the external effectiveness evaluation, CCH Compliance has developed a workplan with associated timelines to facilitate implementation of recommendations for improvement to the CCH Compliance Program.

- Safeguard Protected Health Information (PHI): Continue emphasis on the importance of safeguarding PHI as required by HIPAA while also introducing staff to heightened privacy requirements for specially protected classes of patients. This includes strengthening guidance documents, policies and procedures and updating education material.

- Ongoing monitoring of regulatory changes.

II. Introduction

CCH Compliance Program incorporates two (2) distinct Compliance Programs: encompassing CCH as a provider of health care services including the public health department and the CountyCare Medicaid Health Plan with executive oversight of both programs by a Chief Compliance & Privacy Officer. New in FY21, CCH Compliance established a Research Compliance Program in response to the significant increase in requests for research-related review and approval. In looking at the breadth of Compliance at CCH, system-level services occur within both CCH hospitals (John H. Stroger, Jr. Hospital of Cook County and Provident Hospital of Cook County), multiple outpatient clinics comprising the Ambulatory Community Health Network (ACHN), correctional medicine at the Cook County Jail and Juvenile Temporary Detention Center, and the Cook County Department of Public Health. It also includes providers, clinicians and others that provide direct care to patients, in addition to workforce members not directly involved in patient care. In an indirect way, CCH Compliance also encompasses all of CCH's "business associates" – parties who have contracted with CCH and have access to our patients' and members' protected health information (PHI) in varying capacities.

Although both the CountyCare Medicaid Health Plan CCH Compliance Program and Research Compliance Program are addressed through separate annual reports, all Compliance programs are organized to function at the overarching organizational level and are designed to promote a culture of compliance within CCH as a whole. CCH Compliance has outlined and enforced the expectation that all workforce members are responsible for prevention, detection, and reporting of instances that may not comport with state, federal, or local law, or CCH policy.

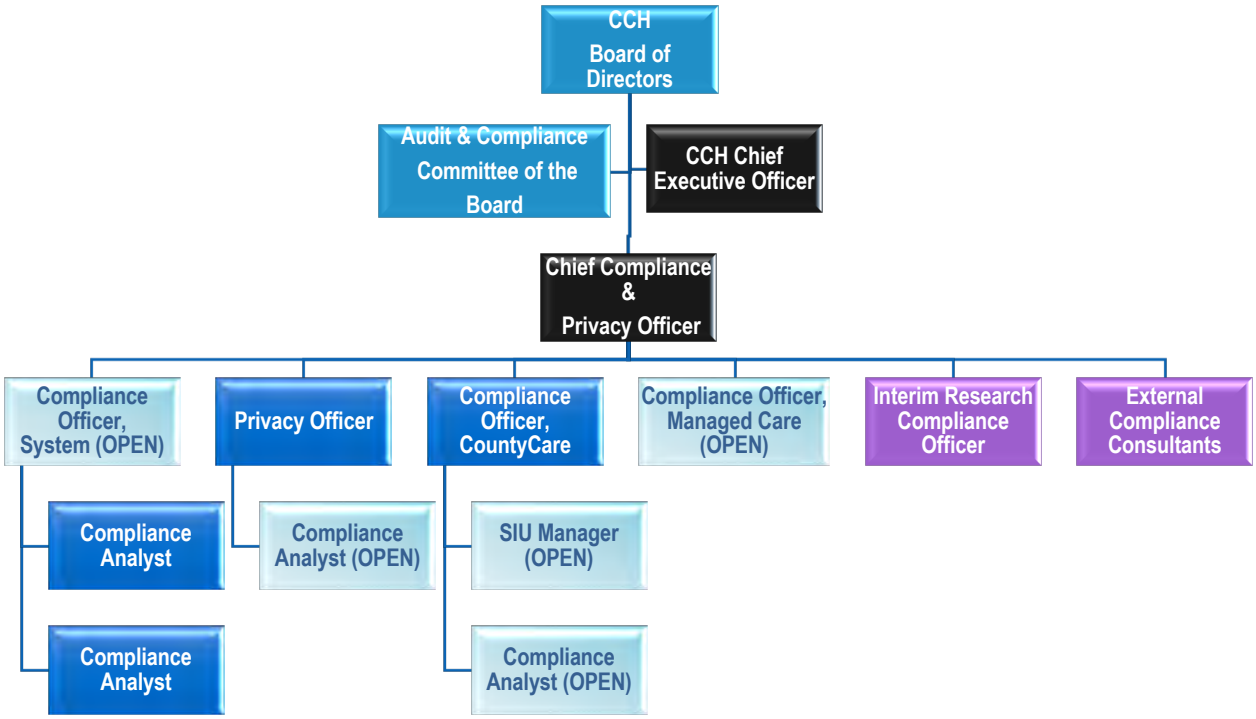
The Annual Report presents the key activities throughout the county fiscal year 2021 (FY 2021) of the System CCH Compliance Program under the executive leadership of Cathy Bodnar, Chief Compliance & Privacy Officer, with support by Dianne Willard, Compliance Officer, Ashley Huntington, Privacy Officer, Compliance Analysts, and other external compliance resources to assist with critical projects and temporarily fill staffing openings. Note that in September 2021, Dianne Willard retired from CCH and her role is now vacant. Cathy Bodnar retired in November 2021 and prior to doing so, welcomed Nicole Almiro as the new Chief Compliance & Privacy Officer.

This report also serves to demonstrate the effectiveness of the compliance program by looking at infrastructure, communication strategy and the methods or channels of communication. In addition, this report provides an assessment of the CCH Compliance Program by examining the seven (7) Compliance Program Elements as recommended in the Department of Health and Human Services (HHS) Office of Inspector General (OIG) Compliance Program Guidance publications. The System Compliance Program is designed to demonstrate the CCH's ongoing commitment to promoting ethical and lawful conduct consistent with all applicable laws, rules, and regulations, as well as CCH policies, procedures, and the Code of Ethics.

III. Building Blocks – Program Infrastructure and Scope

The Annual Report begins with a look at the activities of the Program that foster an infrastructure that produces a comprehensive compliance program. The existing departmental organization chart follows:

Compliance Organizational Chart



CCH Compliance experienced continued staffing shortages in FY 2021. As mentioned in the FY2020 Annual Report, the Compliance Officer supporting CountyCare operations resigned in February 2020. Since that time, CCH Compliance engaged in a lengthy search, recruitment, and interview process. In late September 2021, a new CountyCare Compliance Officer, John Tao, was hired. The Compliance Analyst positions that were eliminated during the CCH budget staff reduction still remain unfilled. Similarly, the Compliance Analyst role under the Privacy Officer, which became vacant in November 2020, remains vacant with interviews currently being conducted.

Nevertheless, due to the significant staffing shortages, CCH Compliance continued its interdepartmental workload redistribution, with emphasis on CountyCare Compliance issues being exclusively managed by the CCH Compliance team for a large portion of FY2020 and a majority of FY2021 until the new CountyCare Compliance Officer, John Tao, was onboarded. Specifically, the CCH Compliance team continued managing all Privacy related issues for CountyCare, including breach analysis and notification, and data sharing requests and guidance; responded to subpoena and subrogation requests; managed provider alerts and stand down

notices; and both coordinated and participated in regular leadership meetings, meetings with delegated vendors, and meetings with CountyCare's regulators. The department also continued its engagement with longtime department consultants, Strategic Management, LLC to assist with critical CountyCare and Privacy projects and support the overall success of Corporate Compliance.

CCH Compliance previously partnered with the Department of Human Resources and local universities to offer internship opportunities to Masters-level and law school students. Due to the ongoing PHE and CCH Compliance's commitment to serving CCH first, the internship opportunities have been suspended indefinitely.

CCH Compliance Program Scope

CCH Compliance continued to serve as a subject matter expert in many areas in FY 2021. CCH activities that fall into the CCH Compliance purview include:

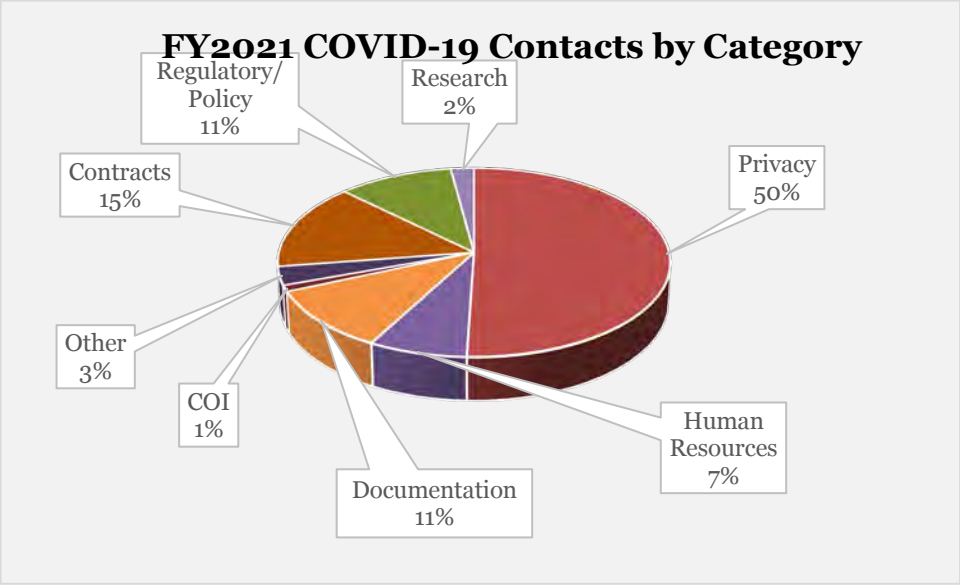
- Interpretation of federal, state, and local laws, rules, and regulations and dissemination of pertinent information to CCH workforce;
- Maintenance and enforcement of the CCH Code of Ethics;
- Assessment and reassessment of CCH Compliance policies and procedures;
- Investigation of allegations of inaccurate books and records including but not limited to merged and tangled medical records, allegations of identity theft, lack of appropriate consents and Attending provider attestation in medical records;
- Evaluation and guidance on potential conflicts of interest;
- Review of contracts/agreements, including business associate agreements, data use agreements, research grants, clinical trials, and master service agreements;
- Watchdog for fraud, waste, abuse and financial misconduct;
- Identification of risks within the organization through auditing and monitoring;
- Monitor for integrity in marketing and purchasing practices; and
- Safeguard privacy, confidentiality, and security of PHI under HIPAA and related federal and state privacy and confidentiality laws.

IV. Ongoing COVID-19 PHE Related Activities

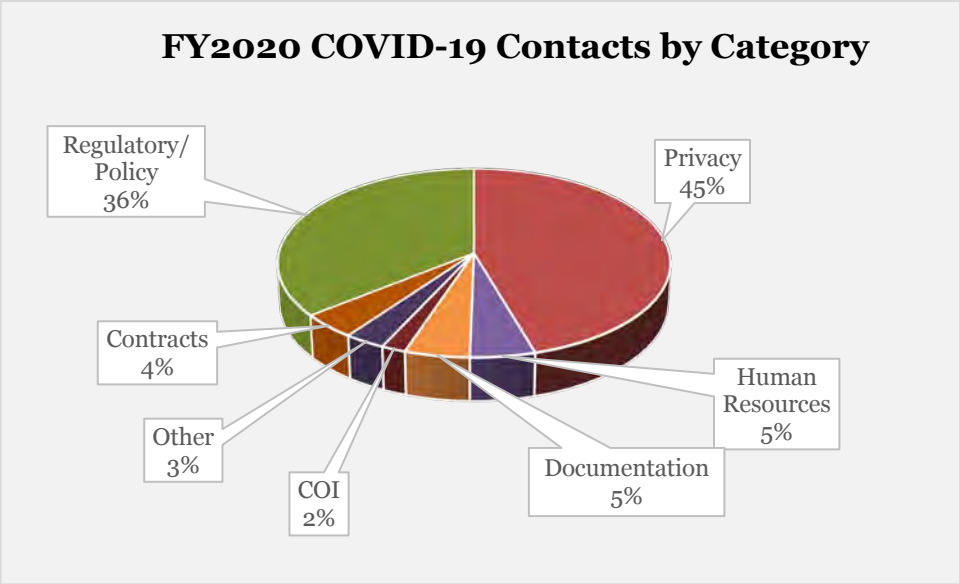
As with FY2020, CCH Compliance's FY2021 work continued to be impacted by COVID-19. In contrast to FY2020, the department maintained an on-site presence of all of its staff for almost the entirety of FY2021. It also carried on its responsibilities for serving as a primary resource for CCH to monitor, interpret, and provide guidance on a rapidly changing regulatory landscape. Because the situation with COVID-19 remains fluid, the department remained flexible and innovative in withstanding the challenges of finding new, effective ways to be present for the organization.

As reported in the FY2020 Annual Report, CCH Compliance received its first COVID-19 related contact on March 12, 2020. During FY2020, the department responded to a total of 165 unique contacts related to COVID-19. In FY2021, the department responded to a total of 95 unique

contacts related to COVID-19. A breakdown of the categories where COVID-19 related inquiries follow, as well as a year-over- year comparison:



Category	Count	Category	Count
Privacy (HIPAA)	48	Contracts	14
Regulatory/Policy	10	Human Resources	7
Human Resources	7	Other	5
Documentation	10	COI	1



Category	Count	Category	Count
Privacy (HIPAA)	75	Contracts	7
Regulatory/Policy	59	Human Resources	3

Human Resources	8	Other	5
Documentation	8		

As demonstrated above, in FY2021, CCH Compliance received 48 unique contacts related to both COVID-19 and HIPAA. This accounts for 50% of the total COVID-19 related contacts received by the department. Of these contacts, a majority pertained to requests for guidance on the ways in which CCH can use and share COVID-19 related PHI.

In FY2021, CCH Compliance provided guidance on the following essential topics:

- Privacy and security considerations and requirements when:
  - conducting telehealth appointments;
  - using Amazon Echoes in the intensive care unit (ICU);
  - sharing the PHI of COVID-19 patients among public health authorities for surveillance purposes;
  - accessing, using, and disclosing of CCH workforce COVID-19 test results and vaccination status;
  - rolling out virtual appointment scheduling for COVID-19 vaccinations for CCH workforce, patients, and the general public;
  - contracting with community partners through the Cook County Department of Public Health (CCDPH) to facilitate a wider reach with COVID-19 vaccinations;
  - allowing regulators and research partners to remotely audit and monitor activities at CCH; and
  - COVID-19 related clinical research agreements involving the use, disclosure, storage, and transmission of research subjects' PHI.

- Regulatory/Policy inquiries presented regarding:
  - monitoring COVID-19 vaccine scheduling processes to ensure CCH policies were adhered to, particularly for scheduling existing CCH patients first and not using CCH patient appointments for staff family and friends;
  - Illinois Department of Public Health's (IDPH) rule regarding hospital workers, COVID-19 testing and vaccination;
  - ongoing regulatory guidance pertaining to telehealth visits and billing for telehealth;
  - opining on requirements for documentation of services conducted through telehealth in addition to providing guidance for documentation when a patient did not attend a scheduled telehealth visit; and
  - supporting communication between Health Information Management, Clinical Areas and Revenue Cycle to ensure compliant procedures.

CCH Compliance anticipates providing support on COVID-19 related issues into FY2022.

V. Being Present – Communication – Fostering Transparency

Communication Strategy

As with previous years, CCH Compliance worked toward its goal of establishing and maintaining visibility and accessibility to CCH workforce, patients, and members, where appropriate. Visibility remained challenging as the entire CCH workforce continued adjusting to work life during the ongoing COVID-19 PHE. Although Compliance strategically decided against in-person training due to the large number of workforce still working remotely and safety issues with gathering groups of people together, CCH Compliance strived toward increasing CCH workforce awareness of the following topics:

- Accessibility of the System CCH Compliance and Privacy teams;
- Availability through multiple modalities (in-person, email, phone, hot-line; virtual meetings);
- Compliance with the Code of Ethics;
- Responsibilities regarding privacy, confidentiality, and security of PHI;
- Requirements to report potential/actual Compliance-related issues; and
- Zero-tolerance for retaliation.

With the ongoing focus on COVID-19, CCH Compliance also spent considerable time dedicated to increasing the CCH workforce's awareness of heightened privacy, confidentiality, and security requirements, particularly during a time when the media, governmental bodies, and general public were seeking information on the PHE, especially the rollout of COVID-19 vaccinations.

Communication Channels

Within the unique challenges posed in FY 2021, CCH Compliance used many modalities to communicate the aforementioned topics including:

- Email communications, particularly to the CCH workforce members requesting guidance on topics such as privacy rules surrounding PHI sharing and CCH policy interpretation and application.
- New employee orientation. Previously, new employee orientation was done exclusively in person, on-site at CCH. In early FY2021, the Department of Human Resources continued presenting the entirety of orientation without presenters, as was done in FY2020 in response to COVID-19. Presenters were asked to resume attending in-person orientation for the latter part of FY2021.
- Annual education for all CCH workforce on compliance topics including the CCH Code of Ethics, Privacy, and Fraud, Waste & Abuse.
- Attendance/presence at team meetings and serving on a number of committees and facilitation of multi-departmental workgroups.

VI. Compliance Program Structure: Performance of the Elements

Element 1

The development and distribution of written Code of Ethics, as well as written policies and procedures that promote the hospital's commitment to compliance (e.g., by including adherence to compliance as an element in evaluating managers and employees) and that address specific areas of potential fraud, such as claims development and submission processes, coding and billing risk areas, and financial relationships with physicians and other healthcare professionals.

The CCH Code of Ethics applies to all CCH personnel, providers, agents, and subcontractors. The Code of Ethics, as well as CCH's policies and procedures, support the organization's commitment to comply with all federal and state standards, including but not limited to, applicable statutes, regulations and sub-regulatory guidance and contractual requirements and is reviewed on a regular basis.

Policies and Procedures

Developed, updated, and performed triennial reviews on multiple system policies related to general compliance, governance, and privacy regulations such as HIPAA, 42 CFR Part 2, and state privacy laws. Functioned as a reviewer for numerous organizational policies with compliance, privacy, and/or security elements.

Served as a key stakeholder on the CCH Policy Review Committee and provided regulatory guidance and leadership to ensure policies were uniform throughout the organization.

Work Plan Activities

- In addition to policy and procedure activity, CCH Compliance worked internally within the department and externally with several CCH operational areas to assess compliance with regulatory requirements. Below is an overview of notable activities:
    - Responsible for regulatory guidance and auditing and monitoring during rollout of COVID-19 vaccinations to staff, CCH patients, and the general public.
    - Worked with executive leadership, medical staff, and the Office of the General Counsel to compile regulatory requirements and provide guidance on compliance components.
    - Tested functionality of all aspects of online vaccine appointment scheduling.
    - Assessed privacy and information sharing issues related to employee COVID-19 vaccinations and provided guidance on the parameters under which CCH could share this information.
    - Conducted auditing and monitoring of COVID-19 vaccination appointments to ensure appointments were scheduled in accordance with Centers for Disease Control and Prevention (CDC) guidance and CCH policy and investigated instances of reported non-compliance.

- Provided significant review and guidance when approached with increased requests to share CCH PHI.
    - As part of CCH Compliance's comprehensive Privacy Program, unique instances of requests for information sharing were reviewed, vetted, and given guidance on whether and how moving forward was possible.
    - Throughout FY2021, CCH Compliance noted an increase in vendors and partners requesting access to CCH PHI.
    - Compliance notes that many of these requests were done on a proactive basis, showing that the CCH workforce views CCH Compliance as a trusted resource.

- Established a Research Compliance Program and Research Compliance Committee.
    - Engaged longtime Compliance consultants, Strategic Management, LLC to review research processes within the organization.
    - Collaborated with key stakeholders, including Research leadership, the Office of the General Counsel, Health Information Systems (HIS) Security, and Internal Audit to define the review process for research at CCH.
    - Created a Research Compliance Committee comprised of a multi-disciplinary team. Voted on and approved a Research Compliance Committee charter.

- Collaborated with executive leadership and the Office of the General Counsel to create review processes for contract reviews.
    - Met with Chief Executive Officer (CEO) Israel Rocha to understand desired review and approval process for contracts.
    - Collaborated with the Office of the General Counsel and Supply Chain Management to establish a new review process and educate key reviewers on changes to the process.
    - Implemented a cover sheet system through DocuSign in which each reviewer signs off that their review is complete, and the contract is approved to move forward for CEO signature.

- Audited New Hire Sanction Screenings Performed by the Department of Human Resources.
    - CCH Compliance audited the Department of Human Resources to determine if sanction screening is completed on all new hires in accordance with the CCH Sanction Screening policy.
    - Currently, an outside vendor performs monthly, and annual sanction screenings of employees and recommendation was made to outsource new hire sanction screenings as well.

- Tackled Responsibilities Set by Local Government Records Management
    - Initiated review of the Record Retention Schedule for Cook County Health that addresses current record retention regulatory requirements and assimilates

categories for user-friendly reference. As a government entity, all documents must be reviewed to determine if they are considered "public records[1]."
  - CCH follows an approved Application for Authority to Dispose of Local Records, known as the Record Retention Schedule. The Schedule dates back to 1985 and contains 1,237 pages with 4,395 listed records and the associated retention periods.
  - CCH Compliance conducted an organization-wide inventory and determined records to be maintained and the duration for which they are currently maintained. CCH Compliance took under consideration federal, state, and local retention requirements, the recommendations of accreditation and professional organizations, the impact of the records on continuity of patient care and system operations along with the likelihood of future utilization retrieval of stored records.
  - Submitted Proposed Record Retention Schedule for Cook County Health to the state Records and Information Management Division for review.
  - Answer from state Records and Information Management Division on the updated Record Retention Schedule expected early 2022.

- Trained and Educated through the online Adobe System
  - Functioned as subject matter expert for three (3) mandatory education modules: Code of Ethics; Fraud, Waste and Abuse; and Privacy. Modules are reviewed annually to assure compliance with regulatory and contractual requirements.

- Facilitated Annual Dual Employment Surveys
  - Pursuant to Cook County's Ethics Ordinance, CCH Dual Employment Policy and Article 12 of CCH's Personnel Rules, all employees must complete a survey annually.
  - The application requires attestations by each employee for compliance with the Dual Employment policy and the Conflict-of-Interest policy.
  - This is the third year utilizing the existing CCH Salesforce software application.

Element 2

The designation of a Chief Compliance Officer and other appropriate bodies, e.g., a CCH Compliance Committee, charged with the responsibility of operating and monitoring the compliance program, and who reports directly to the CEO and the governing body.

[1] A "Public Record" means any book, paper, map, photograph, born-digital electronic material, digitized electronic material, electronic material with a combination of digitized and born-digital material, or other official documentary material, regardless of physical form or characteristics, made, produced, executed or received by any agency or officer pursuant to law or in connection with the transaction of public business and preserved or appropriate for preservation by such agency or officer, or any successor thereof, as evidence of the organization, function, policies, decisions, procedures, or other activities thereof, or because of the informational data contained therein. Found at https://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=699&ChapterID=11

Compliance Office and Committees

The graphic that follows illustrates the communication and reporting structure. As noted above, department leadership changed in FY21 with the retirement of Cathy Bodnar and the onboarding of new Chief Compliance & Privacy Officer, Nicole Almiro. The Chief Compliance & Privacy Officer, reports to the CCH Audit & Compliance Committee of the Board and the CCH Chief Executive Officer. In turn, the CCH Audit & Compliance Committee of the Board and the CCH Chief Executive Officer each report to the CCH Board of Directors.

The primary duties of the **Chief Compliance & Privacy Officer** include the following:

- Provides oversight and guidance to the Board of Directors, Chief Executive Officer and senior management on matters relating to compliance.
- Monitors and reports results of organizational compliance/ethics efforts. Authorized to implement all necessary actions to ensure achievement of the objectives of an effective compliance program.
- Works in conjunction with the Privacy Officer to assure compliance with HIPAA and state laws regarding protection of patient and member health information.
- Monitors the performance of the Compliance Program and related activities, internally throughout CCH and externally for delegated entities, taking appropriate steps to improve effectiveness.
- Develops, initiates, maintains and revises policies, procedures and practices concerning CCH Compliance for the general operation of CCH and its related activities including those to ensure compliance with the CCH Managed Care Community Network (MCCN) Agreement with Illinois Department of Healthcare Family Services (HFS).
- Develops and periodically reviews and updates Code of Ethics to ensure continuing relevance in providing guidance to management and the workforce.
- Responds to alleged violations of rules, regulations, policies, procedures and the CCH Code of Ethics by evaluating or recommending the initiation of investigative procedures.

- Acts as an independent review and evaluation body to ensure that compliance issues/concerns evaluated, investigated and resolved, which may include reporting of violations or potential violations to duly authorized enforcement agencies as appropriate and/or required.
- Identifies potential areas of compliance vulnerability and risk; monitors operational corrective action plans for resolution of problematic issues and provides general guidance on how to avoid or deal with similar situations in the future.
- Establishes and monitors a system to log, track and maintain documentation for all concerns/issues raised to Corporate Compliance.
- Institutes and maintains an effective compliance communication program for the organization, that includes (a) promoting the use of the compliance hotline or other mechanisms for communicating with Corporate Compliance; (b) emphasizing to leadership, employees, and workforce members reports of suspected fraud and other improprieties should be made without fear of retaliation; (c) heightening awareness of the Code of Ethics; and (d) understanding new and existing compliance issues and related policies and procedures.
- Works with CCH Human Resource Department and others as appropriate to develop, implement, maintain, and document an effective compliance training program, including appropriate introductory training for new workforce members as well as ongoing training for all workforce members.
- Guides and partners with operational leadership to facilitate operational ownership of compliance. Consults with legal counsel, internal and external, as needed and independently to resolve difficult compliance issues.
- Collaborates with operational areas throughout the organization to direct compliance issues to appropriate channels for investigation and resolution.

The **Audit & Compliance Committee of the Board** advises the CCH Board of Directors regarding the implementation of standards and processes to assure professional responsibility and honest behavior, compliance with regulatory requirements, and risk management.

In addition to the aforementioned relationships, the Chief Compliance & Privacy Officer receives support and guidance from the internal **CCH Compliance Executive Steering Committee**, an assembly of executive leaders within CCH, including but not limited to, the CEO, Deputy CEO, System Director of Internal Audit, Chief Information Officer, Chief Medical Officer, Chief Nursing Officer and others.

Element 3

The development and implementation of regular, effective education and training programs for all affected employees.

Education and Training

1. New Employee Orientation

Prior to the COVID-19 PHE, CCH Compliance attended New Employee Orientation once every two weeks to present an "Introduction to CCH Compliance and HIPAA." In response to the PHE, the Department of Human Resources requested departments develop material to address their respective areas. CCH Compliance developed a presentation to address the subject matter routinely presented and Human Resources presented the material for approximately the first half of FY21. Presenters were asked to resume attendance at New Employee Orientation on July 6, 2021. Compliance presented its materials every two weeks from that time for a total of approximately 11 in-person presentations in FY21.

2. Targeted Education

   Prior to the PHE, CCH Compliance worked with departments across CCH to provide targeted refresher training. Typically, this occurs either when a department leader requests training or when a HIPAA breach or incident occurs in a department and retraining is needed. Given the challenges with gathering in groups due to COVID-19, the departments and CCH Compliance found it more effective to provide guidance in written form.

   Although the details of the CountyCare Compliance Program will be addressed in a separate report, the Privacy Officer, in collaboration with external compliance consultants from Strategic Management, LLC, created an extensive Privacy training for CountyCare Care Coordinators at the request of CountyCare leadership. This training was developed over several months and included regular check-in calls with care coordinators to ensure key areas of concerns were addressed. The final training deck was delivered to CountyCare Care Coordination in late FY21. In early FY22, Privacy will work with the care coordinators on a "train the trainer" arrangement to deliver this training to new care coordinators.

3. Annual Compliance Education

   As noted earlier, responsible for three (3) mandatory education modules: Code of Ethics; Fraud, Waste and Abuse; and Privacy.

Element 4

The maintenance of a process, such as a hotline, to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation.

Receiving and Responding to Complaints

Infrastructure Activities

1. Assisted our workforce members through:
   - A hotline service provided by an independent, contracted third-party to preserve caller anonymity if desired. The individual is given a code number related to their report and can call back or check the website using that code number to review comments and updates. In FY21, 51 calls or internet/online inquiries were received on the hotline.
   - A separate toll-free number for patients and members to contact following notification of a privacy breach.

- Collaboration with operational areas, including, but not limited to, General Counsel, Human Resources, Health Information Services (HIS), Patient Relations, Revenue Cycle, Research, and Health Information Management (HIM) to assist in resolving compliance-related issues.

2. Maintained three (3) email addresses for CCH Compliance:
   - Compliance (compliance@cookcountyhhs.org)
   - Privacy (privacy@cookcountyhhs.org) and
   - CountyCare Compliance (countycarecompliance@cookcountyhhs.org).

3. Engaged internal and external resources to assist in complex compliance and privacy research which, in the case of external resources, provided governmental and national perspectives on compliance issues.

4. Identified trends and patterns in enforcement actions to mitigate organizational risks and facilitate operational improvement, including:

   - Evaluating CCH's compliance with right of access provisions under the HIPAA Privacy Rule.
     - CCH Compliance noted a significant uptick in enforcement actions by the Office for Civil Rights (OCR) related to right of access violations.
     - Worked with HIM to update Right to Inspect policy to bring it into alignment with regulatory requirements.
     - Partnered with HIM to resolve complaints from patients, attorneys, and regulators that records requests were unfulfilled or delinquent.
   - Assisted a multi-disciplinary team to ensure that patients are billed for the correct Level of Care.
     - CCH Compliance worked with a high level multi-disciplinary team to ensure that patients are being billed accordingly to the level of care provided, not the location of their bed. Compliance has provided regulatory guidance and assistance in the revision of new report that generates the daily level of care throughout the hospital. CCH Compliance communicated the need for improved documentation of level of care within the electronic health records and re-education for providers. Additionally, three (3) separate Level of Care audits were conducted by CCH Compliance to determine if guidance and new report improved compliance.
   - Collaborated with Stroger Hospital Police on investigations pertaining to compromised Drug Enforcement Administration (DEA) registration numbers for fraudulent prescriptions.
     - Provided guidance to providers on how to address and monitor stolen DEA registration numbers. Additionally, partnered with external pharmacies to ensure appropriate measures are taken to prevent future fraudulent activities.

- Provided continued compliance guidance and monitoring for the Sexual Assault Survivors Emergency Treatment Act (SASETA) Task Force.
  - Worked with the Task Force to increase compliance with regulatory requirements for photo-documentation storage, retention, and access.
  - Assisted in review and approval of system-wide policies and procedures for photo documentation and management of a sexual assault or abuse survivors for both adult and pediatric patients.
- Continued administration of the Avoiding Tangled Records Policies and Procedures.
  - Collaborated with Patient Access and HIM to ensure that incorrectly merged or tangled records are corrected promptly.
  - Determined appropriate refund or recoupment, if applicable, and partnered with the Revenue Cycle department for prompt processing.
- Partnered with leadership of Patient Access department and HFS to ensure that the Financial Assisters process for completing Medicaid applications is compliant with HFS standards.
  - Concluded in re-education of the Patient Access department with input from HFS.
- Investigated allegations of CCH workforce members scheduling COVID-19 vaccines in appointments slots intended for CCH patients.
  - Following an incident during which an employee attempted to use a COVID-19 vaccination appointment slot allocated for CCH patients, an investigation was conducted to confirm that patients were given priority for hard to come by appointments.
  - Conducted ongoing monitoring to ensure CCH policies and procedures for COVID-19 vaccinations were followed.
- Corrected documentation in Cerner caused by input of incorrect COVID-19 vaccine lot numbers.
  - Worked with ACHN leadership and Communications after reporter contacted CCH regarding incorrect COVID-19 lot numbers on the vaccination cards.

5. Presented trends and patterns to the CCH Compliance Executive Committee and the Audit and Compliance Committee of the Board.

<u>General Processes for Responding to Inquiries, Issues and Complaints</u>

The workflow process for compliance contacts follows SBAR, an acronym for **S**ituation, **B**ackground, **A**ssessment, **R**ecommendation.

Initially, CCH Compliance is made aware of a **S**ituation,

- Contact is made through one or multiple modalities e.g., via email, direct phone call or call through the compliance hotline, email, and/or in-person;

- An inquiry is made, or a concern is described;
- An individual(s), area(s) or situation is identified.

This **B**ackground information is classified, compiled and logged in the CCH Compliance tracking tool.

An **A**ssessment occurs,

- Research and review organizational policy, federal, state, and county regulations to evaluate the situation presented;
- Determine what the problem is and/or the severity.

Lastly, the **R**ecommendation,

- Establish a pathway for mitigation and remediation. These may include further auditing of documentation, mitigating harm, and potentially informing the appropriate government entity.
- This always involves engaging and collaborating with leadership.
- Share recommendations with the reporter, as appropriate.

The work-flow process for potential HIPAA incidents and breaches similarly follows SBAR. However, if the **A**ssessment determines a reportable breach has occurred then,

- HIPAA breach notification rules regulatorily require sending a notification letter to the affected individual(s) within 60 days of discovery.
- Notification to the Office for Civil Rights (OCR) annually.

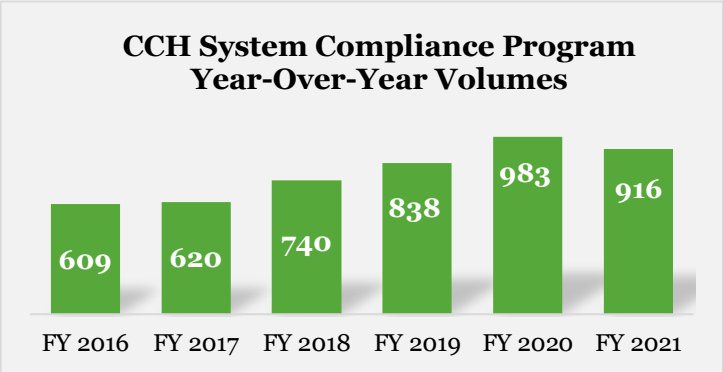
Breaches that affect over 500 individuals must include the following,

- Releasing a statement to prominent media outlets serving the state;
- Posting a notice on the CCH website; and
- Notifying the Office for Civil Rights (OCR) within sixty (60) days of discovery.

Similarly, collaboration with the operational area to determine and facilitate a corrective action plan which includes re-education. The diagram that follows illustrates the approach to incident investigation and ensures that all the causes are discerned and addressed by appropriate actions.

Contact Volumes

In FY 2021, 916 identified contacts were documented for the CCH Compliance Program. The chart that follows illustrates the year-over-year activity. CCH Compliance Program notes that while FY21 shows a slight decrease in unique contacts, significant time and effort were spent on larger scale projects, such as the COVID-19 vaccine rollout, establishing a Research Compliance Program, and exclusively managing CountyCare's contacts for 10 months of FY21. Compliance also believes its effectiveness is not only demonstrated by an increase in contacts. Rather, Compliance is encouraged that the guidance it gives allows departments to evaluate and manage similar occurrences in the future without the need for Compliance involvement.



Contact Breakdown by Category

Categories defined below parallel the CCH Code of Ethics. The inclusion of a contact in a specific category does not substantiate the contact as a concern; rather it classifies the contact within a defined category.

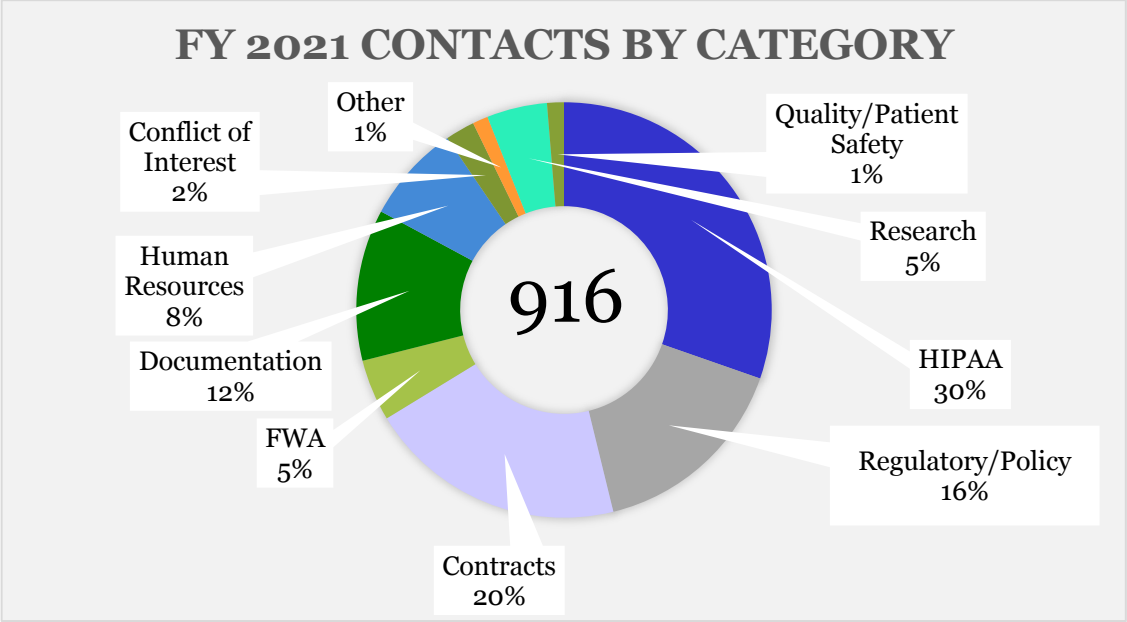
In FY 2021, CCH Compliance continued use of its modified internal tracking system to utilize a COVID-19 check box to identify any COVID-19 related compliance issues that emerged during the pandemic. FY 2021 categories are as follows:

- Conflict of Interest
- Contracts/Agreements
- Documentation
- Fraud, Waste and Abuse, and Financial Misconduct
- HIPAA Privacy, Confidentiality and Security
- Human Resources
- Quality/Patient Safety
- Regulatory/Policy
- Research
- Other (Comprised of contacts that may include theft and miscellaneous compliance topics)

FY 2021 Contacts by Category

As with prior years, HIPAA Privacy, Confidentiality, and Security continues to comprise the largest share of contacts that come to Corporate Compliance. In FY 2021, 278 or 30% were categorized within this category. This shows a slight decrease as compared to previous years which can be attributed to the following: CCH Compliance previously reviewed research clinical trial agreements from only a privacy perspective, thus classifying those contacts under HIPAA Privacy, Confidentiality, and Security. Also, contracts and business associate agreements are classified under Contracts rather than HIPAA. Approximately 22 or 7% of HIPAA Privacy, Confidentiality, and Security contacts were confirmed privacy breaches that required notification to 248 patients.

It should be noted that the Privacy Officer and the System Compliance team investigated, managed, and followed reporting obligations for a breach impacting more than 500 CountyCare members caused by a subcontractor of one of CountyCare's vendors, First Transit. In response to this report, the Office for Civil Rights (OCR) sent an investigation notice to CCH which requested documentation on the breach as well as CCH's policies and procedures and mitigation efforts. The Privacy Officer compiled the requested documentation and responded to OCR in September 2021.



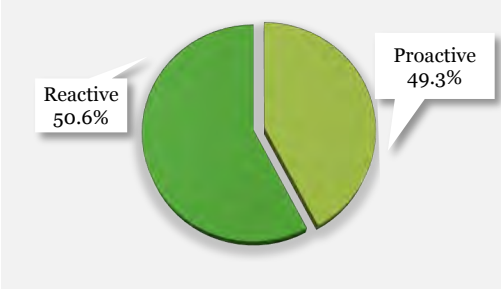
Categories	Count	Categories	Count
Privacy/Security (HIPAA)	278	Contracts	184
Documentation	108	Conflict of Interest	21
Regulatory/ Policy	145	FWA	44
Human Resources	70	Other	11
Research	43	Quality/Patient Safety	12

FY 2021 Contact Status

Of the 916 contacts throughout FY 2021, 872 contacts were resolved at the end of the fiscal year. The remaining 44 contacts carried into FY 2022. Of the contacts resolved, 866 or 94%were either managed internally by CCH Compliance or CCH Compliance partnered with another area to address the concerns raised. This metric is consistent year-over-year.

FY 2021 Proactive vs. Reactive

It has been a longstanding goal of CCH Compliance to restore balance to the number of proactive versus reactive contacts that come into the department. As demonstrated by the below data, the System Compliance team has made great strides toward this goal, with proactive and reactive contacts nearly equal for the first time since Compliance began tracking this specific data point.



Of the 916 System Compliance contacts managed during FY 2021, 464 contacts or 50.6%were reactive. Reactive contacts occur in response to an action that has already been initiated. On the proactive side, 49.3%or 452 contacts were classified as proactive. The proactive category is defined as questions brought to the attention of CCH Compliance by individuals seeking guidance prior to the occurrence of an event or activity. FY 2021 showed a 12% increase in proactive contacts from 37%FY 20120. Compliance is immensely encouraged by the positive trend towards individuals seeking guidance prior to embarking upon an action.

Element 5

The development of a system to respond to allegations of improper/illegal activities and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations, or Federal health care program requirements.

Enforcing Standards

Broadened the scope of Standards enforcement through:

- Breach Assessments. Reviewed investigations and provided remediation guidance to operational areas to minimize and/or eliminate breaches in the future and utilized the CCH Sanction Policy and Personnel Rules, to provide leadership guidance for disciplinary action.

- Breach Notification. Investigated all instances of lost or stolen patient information, including paper and electronic. For all instances in which the data loss constitutes a breach as defined by the Breach Notification Rule, the breach notification requirements to the patient, the Secretary of HHS, and the media are completed. Corrective action plans are created and executed to improve the processes and counsel the physicians and employees involved.

- Conflict of Interest. Provided guidance and developed Conflict Management Plans to preserve the integrity of the decision-making process.

- Investigations Resulting in Employee Related Corrective Actions. HIPAA and Conflict of Interest complaints were investigated and resulted in providing leadership guidance to remediate the situations and avoid repetition of the incident.

- Partnerships with Governmental Agencies. CCH Compliance has engaged both state and federal agencies (e.g., the Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), Office for Civil Rights (OCR), Federal Bureau of Investigations, Department of Healthcare and Family Services (HFS), HFS Office of the Inspector General, and the Medicaid Fraud Control Unit) on a variety of matters. Additionally, Compliance has worked with the Cook County Office of the Independent Inspector General.

Element 6

The use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem area.

Auditing and Monitoring

Privacy Auditing and Monitoring. The Privacy side of the CCH Compliance conducted ongoing Privacy auditing and monitoring of access to the electronic health record by:

- Investigating all allegations of inappropriate access to the electronic record;
- Utilizing the auditing tool, Cerner P2Sentinnel, to run reports showing access to certain electronic health records;
- Working with operational leadership to take appropriate disciplinary action and educate staff when inappropriate access is determined; and
- Collaborating with HIS to review prior security audits and identify key areas of risk to address in FY 2021 and moving forward.

Coding Audit. The CCH Compliance Program engaged an independent third party to perform an External Coding Audit based on a Corrective Action Plan (CAP) for a vendor utilizing Artificial Intelligence (AI). The audit revealed opportunities within the following areas:

- Coding quality and specificity for diagnosis and procedure assignment;
- Improvement through physician documentation and coding nomenclature education; and
- Adjustments with laboratory billing to correct inaccuracies.

Upon completion of external audit, shared audit results with CCH HIM leadership.

Risk Assessment

The CCH Compliance Program risk assessment process is dynamic, and adjustments are made throughout the year to respond to emerging issues with the resources available. This report highlighted activities that minimized risk through the introduction and enforcement of policies and standards, auditing and monitoring, education, and issue investigations with corrective action plans as appropriate.

Through surveys of executive leadership and key thought leaders within the organization, overlying industry risks, and through the course of activities within prior fiscal years, the following areas were identified in FY 2021 as areas of concern:

- Using, disclosing, and safeguarding PHI, in all forms, with emphasis on data security through encryption and other available technologies, remained incredibly important during the COVID-19 PHE and vaccine rollout;
- Establishing a review process for research throughout CCH, culminating in the creation of a Research Compliance Program and Research Compliance Committee;
- Examining patient data to ensure accurate registration and deter identity theft and merged electronic health records;
- Acting as a key stakeholder in contract negotiations and review. Compliance reviews the contract in its entirety with additional focus on areas of compliance, privacy and security, including the review and execution of Business Associate Agreements with business partners that may have access to PHI;
- Assessing documentation supports the services performed through accurate code assignment;
- Assuring sanction screening was performed during the onboarding process for employees and vendors;
- Monitoring the 340B Drug Pricing Program through oversight and participation on the Pharmacy's 340B Committee;
- Evaluating the current Record Retention Schedule for Cook County Health to determine next steps for updating the document to a user-friendly tool; and
- Partnering with physicians to accentuate the need for them to manage their prescription activity with the Illinois Drug Prescription Monitoring Program to eliminate fraudulent controlled substance prescriptions.

Element 7

The investigation and remediation of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals.

Sanction Screening Checks

- A policy and procedure paralleling the requirements set forth by the Department of Health and Human Services, Office of Inspector General, is in place to ensure the screening of all contractors and workforce members.

- The policy is placed to avoid employing, engaging, contracting or agreeing with any individual or entity that is excluded or "sanctioned" from participation in a federal health care program or who is debarred from participation in federal procurement or non-procurement programs for the provision of goods or services.
- CCH screens all employees prior to hire and vendors prior to contracting.
- Delegated vendors attest to screening of all workforce members upon hire and routinely thereafter.
- Corporate Compliance, through an independent third party, is responsible for subsequent screenings. The third-party screens workforce members, employees of delegated vendors that work at CCH locations or have contact with a patient or CountyCare member, monthly and annually.
- Determined, through an independent third party, no excluded or sanctioned CCH workforce members or vendors were identified throughout this fiscal year.

VII. Looking Ahead to 2022

Although the CCH Compliance Program identifies and outlines its large-scale priorities for the upcoming fiscal year, it also remains committed to continuing:

- Serving as a resource to all that require Compliance-related assistance throughout CCH.
- Monitoring the everchanging regulatory landscape and ensuring dissemination and education on compliance matters.
- Responding timely to inquiries, allegations, and complaints brought to the attention of Compliance through all modalities.
- Conducting risk assessments, identifying high and low priority risks, implementing solutions, and strategizing to resolve and/or prevent risk reoccurrence.
- Assessing and reassessing compliance and privacy policies and procedures to ensure they reflect regulatory requirements as well as are appropriate from an operational perspective.
- Engaging in professional development through available compliance educational opportunities.
- Bringing awareness to the CCH Compliance Program, both internally to CCH workforce and externally to patients, members, vendors, and the general public.

Notable priorities for FY 2022 include:

- Compliance Education: Given the ever-changing healthcare regulatory environment, there is a need to update and communicate these changes quickly to employees in a manner that is easily understood and retained. To this end, CCH Compliance will develop 5-minute or less animated educational videos to shorten the lengthy learning topics to smaller units of learning content to reduce information overload, simplify complex topics, and entertain and engage in an effort to enhance retention of and therefore compliance with the topic.

- Research Compliance Program: Continued development of our Research Compliance Program is fundamental for ensuring compliance with the various laws and regulations from multiple agencies and enforcement bodies, educating employees, revising and establishing processes and procedures, and assisting in preventing future problems. Upcoming area of increased focus is clinical trial billing compliance including how CCH patients may be flagged as participating in a research study within the electronic medical record and whether enhanced bill review processes are needed for charges related to research studies.
- Clinical Documentation Education Program: CMS recently made landmark changes to documentation, coding, and billing for evaluation and management services for outpatient visits while evaluation and management services for inpatient services remain unchanged. To enhance compliance with these recent changes, CCH Compliance will develop a clinical documentation education program to heighten awareness and assist providers and staff with these clinical documentation changes that will improve compliance with coding and third-party billing.
- Implementation of Recommendations for Improvement to CCH Compliance Program: Utilizing the Compliance Program Evaluation Report from the external effectiveness evaluation, CCH Compliance has developed a workplan with associated timelines to facilitate implementation of recommendations for improvement to the CCH Compliance Program.
- Safeguard Protected Health Information (PHI): Continue emphasis on the importance of safeguarding PHI as required by HIPAA while also introducing staff to heightened privacy requirements for specially protected classes of patients. This includes strengthening guidance documents, policies and procedures and updating education material.

COOK COUNTY HEALTH

Cook County Research Compliance Program

Annual Report
Fiscal Year 2021
December 1, 2020 – November 30, 2021

January 21, 2022

Table of Contents

I. Executive Summary....3
II. Introduction 4
III. Building Blocks – Program Infrastructure and Scope....6
IV. Research Compliance Program Structure - Performance of the Elements....8
Element 1 - Standards of Conduct, Policies and Procedures....8
Element 2 - Compliance Office and Oversight Responsibilities....9
Element 3 - Education and Training....11
Element 4 - Receiving and Responding to Complaints....11
Element 5 - Enforcing Standards....14
Element 6 - Monitoring and Auditing....14
Element 7 – Prevention & Detection....15
Element 8 – Clearly Defined Roles and Responsibilities....16
V. Looking Ahead to 2022....16

I. Executive Summary

The CCH Research Compliance Program was first introduced at a meeting with CCH executive leadership on February 18, 2021. Research is a heavily regulated environment and as such, having a Research Compliance Program in place is fundamental for ensuring compliance with the various laws and regulations from multiple agencies and enforcement bodies. The development of a Research Compliance Program can aid in identifying legal and regulatory problems, correct deficiencies, and assist in preventing future problems. The CCH Research Compliance Program will also guide CCH as it builds more formal research office functionalities, including a structure for appropriate oversight.

Since the initial introduction meeting, significant activity has occurred to thoughtfully implement the program, alongside other compliance related priorities for the CCH Compliance Program. The Fiscal Year (FY) 2021 Research Compliance Program Annual Report summarizes the primary compliance activities that the Cook County Health (CCH) Research Compliance Program accomplished in FY 2021 and identifies priorities for FY 2022.

In its first year of implementation, the Research Compliance Program accomplished various goals and spearheaded several new initiatives. These achievements include:

- Research Compliance Committee: Developed and implemented an executive level Research Compliance Committee to aid in identifying, assessing and prioritizing research compliance risks. The purpose of the Research Compliance Committee is to advise and assist the CCH Research Compliance Officer in the development, implementation and oversight of CCH's Research Compliance Program.

- Research Compliance Risk Assessment: Initiated a Research Compliance Risk Assessment which focused on identifying current internal controls in place related to key risk areas for research, as observed nationally and as identified internally at CCH.

- Identification of Research Conducted at CCH: Developed an understanding of the scope of research activities conducted at CCH, including a tabulation of all active research studies and grant activities currently underway at CCH during FY 2021.

- Clinical Trial Agreement Review Process discussions: Collaborated with CCH Compliance, the Office of the General Counsel and representatives from Research & Regulatory Affairs and the Center of Health Equity & Innovation to review and streamline the process for review and signature for clinical trial agreements and grants, including the review of agreements and/or contracts that impact CCH protected health information (PHI).

- Federal Research Requirements Review: Review of federal research requirements and development of policies to address Financial Conflict of Interest Disclosure and Federal Contracting (NIH Grants Management Policy and the Federal Acquisition Regulation).

In FY 2022, Research Compliance plans to continue building the recently launched program, with a focus on continued collaboration with the various departments conducting research at CCH to

assess potential risk areas, identify areas of potential non-compliance and work toward strengthening and improving research compliance at CCH.

Notable priorities for FY 2022 include:

- Financial Conflict of Interest audit: Completion of a comparison audit between CCH personnel conflict of interest survey data and financial data from drug and device manufacturers posted on CMS Open Payments website for improvement related to existing disclosures processes.
- Audit Collaboration: In collaboration with the CCH Research & Regulatory Affairs department, review the current schedule of audits conducted and determine where Research Compliance may be leveraged for support for internal and external audit activities.
- Focused Review of Clinical Trial Billing Processes: Review and identify areas of improvement related to uniform clinical trial billing processes at CCH, including how CCH patients may be flagged as participating in a research study within the electronic medical record and whether enhanced bill review processes are needed for charges related to research studies.
- Policy Development: Continued development of the Federal Contracting policy and Financial Conflicts of Interest policy, as well as other policies deemed necessary based on the finalization of the Risk Assessment and upon request from CCH operations.
- Compliance Education: Development of compliance training materials specific to research compliance (in addition to that provided by the Institutional Review Board (IRB)), including materials addressing Financial Conflicts of Interest and newly implemented processes.
- Formalization of the CCH Research Office: Continued collaboration with departments involved in research activities to formalize research office functionalities and responsibilities, including potential identification of a solution for managing and tracking clinical trial activities.
- Regulatory Changes: Ongoing monitoring of regulatory changes impacting Research Compliance.

II. Introduction

The formal CCH Research Compliance Program was initiated and implemented during FY 2021, though CCH Compliance was engaged in review of research agreements in FY 2019 and FY 2020, prior to the establishment of a formal program.

Organizations that conduct Clinical Research are subject to a variety of laws and regulations from multiple agencies and enforcement bodies, as is common in the health care industry. With this in mind, CCH Compliance, in collaboration with CCH executive management and with oversight

from the CCH Audit & Compliance Committee, designed a CCH Research Compliance Program that would fundamentally work towards:

- Aiding in identifying legal and regulatory problems, correcting deficiencies, and assisting in preventing future problems;
- Facilitating compliance with the various laws and regulations from multiple agencies and enforcement bodies, including NIH, FDA, CMS, HFS, OHRP, OCR, ORI, PHS, OMB and more; and
- Providing support to ensure that proper scientific, ethical, and regulatory requirements are followed in research protocols and promoting research integrity throughout the organization.

The Research Compliance Program is focused on all research conducted at CCH, which includes the following:

- Clinical trials and research conducted based on IRB approval, including government funded studies (NIH, FDA, etc.), sponsor funded studies and home-grown research;
- Research grants, including government research grants (DOJ, SAMHSA, etc.) and research funded by private sector/organizations; and
- Grants that do not include "clinical research" per se (i.e., not reviewed by the CCH IRB), but where funds are still received by CCH.

Initial discussions regarding the implementation of the Research Compliance Program began at an internal meeting with CCH executive leadership on February 18, 2021. Subsequent meetings were held with individuals in operational roles within the CCH Research & Regulatory Affairs department, the Center for Health Equity & Innovation and the Finance department. Additional background and progress updates were provided to the Audit & Compliance Committee of the CCH Board on August 20, 2021. Finally, an executive level Research Compliance Committee, tasked with advising and assisting with the development, implementation and oversight of the Research Compliance Program, assembled on September 14, 2021, and November 16, 2021.

The implementation of the Research Compliance Program is essential for demonstrating CCH's ongoing commitment to promoting ethical and lawful conduct consistent with all applicable laws, and regulations, as well as CCH policies, procedures, and the Code of Ethics. All CCH workforce members are responsible for prevention, detection, and reporting of instances that may not comport with state, federal, or local law, or CCH policy, including those who are conducting research activities for or on behalf of CCH.

This annual report serves to summarize the implementation of the Research Compliance Program by looking at the infrastructure of the program, including a summary of eight Compliance Program Elements as recommended in the Department of Health and Human Services Office of Inspector General (OIG) in its Compliance Program Guidance publication addressing Clinical Research. The report also presents the activities throughout the county fiscal year 2021 (FY 2021) of the Research Compliance Program under the executive leadership of the CCH Chief Compliance & Privacy Officer, with support by the CCH Privacy Officer, Compliance Analysts and other

external compliance resources to assist with critical projects and temporarily fill staffing openings.

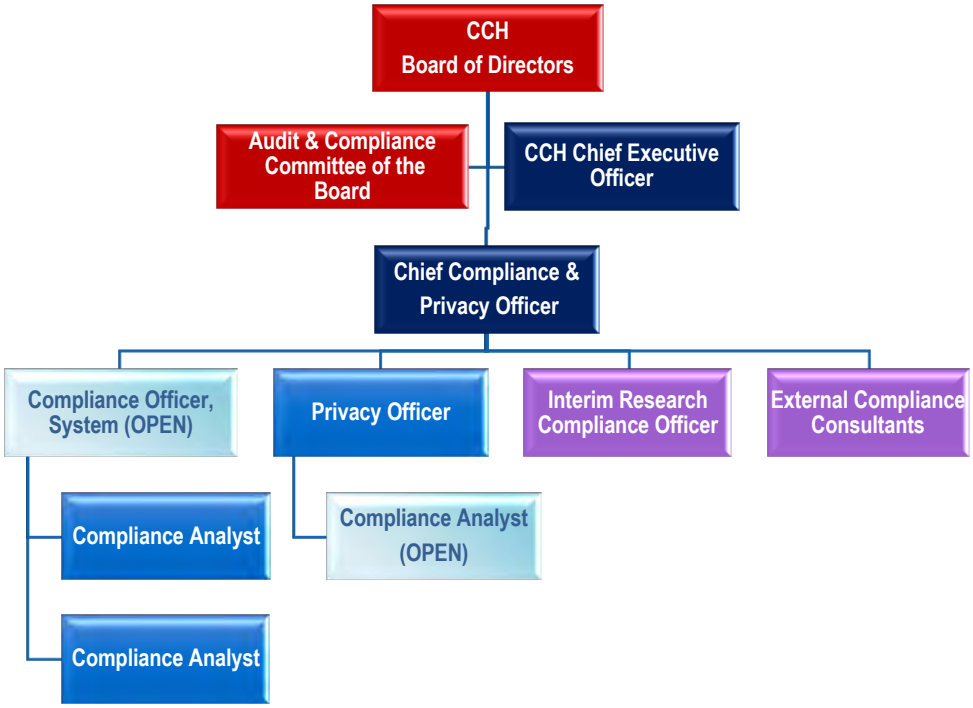
III. Building Blocks – Program Infrastructure and Scope

This Annual Report begins with a review of the efforts taken to design and foster an infrastructure that produces a comprehensive Research Compliance program.

The Research Compliance Program infrastructure relies upon the resources of the existing CCH Compliance department, which experienced continued staffing shortages in FY 2021. As such, the department engaged longtime department consultants, Strategic Management, LLC to assist with performing Interim Research Compliance Officer responsibilities, as well as other responsibilities to support the overall success of Research Compliance.

The existing Departmental Organization Chart follows:

Research Compliance Organizational Chart

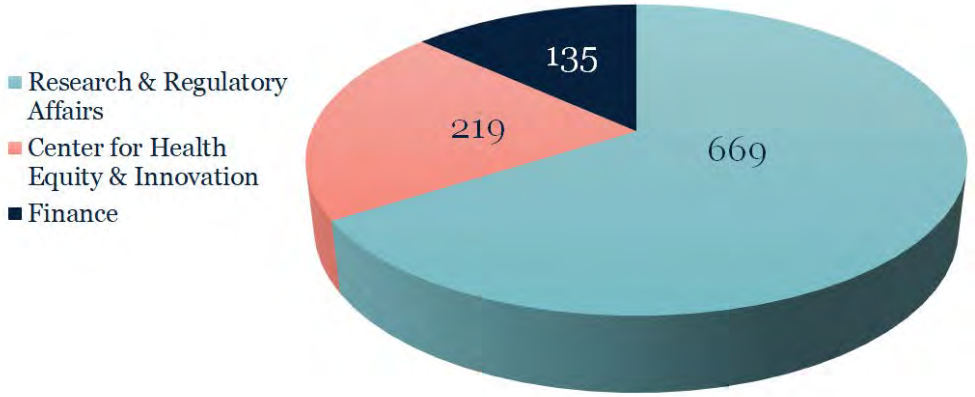


The Interim Research Compliance Officer reports up through the CCH Chief Compliance & Privacy Officer, with a close working relationship with CCH Office of General Counsel, the CCH Research & Regulatory Affairs department, the Center for Health Equity & Innovation and the Institutional Review Board.

Research Compliance Program Scope

As discussed above, the Research Compliance Program is focused on a variety of types of research activities conducted by CCH personnel. The term "research" includes activities that meet the more traditional definition of a clinical trial[1], which undergo review by the CCH IRB (and/or an external IRB) and are managed by the CCH Research & Regulatory Affairs department, as well as activities related to grants provided to CCH by external funding sources (e.g., government agencies, private sector organizations, non-profits, etc.), which are managed by the Center for Health Equity & Innovation and/ or the Finance department.

When informally tabulated in mid-November of 2021, the number of total active research studies identified at CCH was 1,023. The chart below contains a breakdown of the research activities identified per operational area at CCC:



With this scope in mind, CCH activities that fall into the Research Compliance purview include:

- Interpretation of federal, state, and local laws, rules, and regulations and contractual requirements implicating research activities at CCH;
- Creation, review and/or maintenance of policies and procedures addressing research Compliance subject areas;
- Investigation of allegations of compliance related issues impacting CCH research activities;
- Provision of communication and training to the CCH community on research compliance-related matters;
- Review of certain contracts/agreements, including clinical trial agreements and grants, data use agreements, and compliance provisions of master service agreements;
- Evaluation and guidance on potential conflicts of interest for individuals conducting research, in collaboration with the CCH IRB;

[1] Per the National Institutes of Health (NIH), a clinical trial is defined as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." See https://grants.nih.gov/policy/clinical-trials/definition.htm.

- Performance of monitoring and/or auditing efforts to address areas of risk for research;
- Collaboration on any government and/or regulator audits of CCH research activity; and
- Ensuring that the program is structured to prevent, detect, and equitably resolve research compliance issues.

IV. Research Compliance Program Structure: Performance of the Elements

The HHS OIG, in its Draft Compliance Program Guidance for Recipients of PHS Research Awards, emphasizes that institutions should consider implementing eight elements as part of an effective Research Compliance Program. Accordingly, the Research Compliance program was designed and is in the process of implementing each of the suggested elements, as outlined below. Several of the elements outlined below leverage existing structures, processes and/or resources already in place within the CCH Compliance Program.

Element 1

The development and distribution of written standards of conduct and policies and procedures that reflect the institution's commitment to compliance.

Code of Ethics

The CCH Code of Ethics applies to all CCH personnel, providers, agents and subcontractors who conduct research activities on behalf of CCH. The Code of Ethics supports the organization's commitment to comply with all federal and state standards, including but not limited to, applicable statutes, regulations and sub-regulatory guidance and contractual requirements and is reviewed on a regular basis.

Policies and Procedures

Policies and procedures are currently in place within CCH Compliance that address the structural and functional elements of a compliance program, as well as several areas of risk pertinent to research compliance, including conflict of interest and privacy/data sharing. These policies and procedures undergo triennial review.

Additionally, Research Compliance is in the process of developing and implementing several new policies and procedures with applicability to CCH research activities, including the following:

- Development of a Financial Conflict of Interest Disclosure policy (in collaboration with the IRB/Research & Regulatory Affairs department), to address NIH and FDA requirements for reporting financial conflict of interests for research studies; and

- Development of a Federal Contracting policy (in collaboration with Office of General Counsel and Internal Audit) to address requirements within the NIH Grants Management Policy and the Federal Acquisition Regulation (FAR).

Additional efforts are also currently underway to actively identify areas where research related policies and procedures may be needed.

Written Guidance

During FY 2021, the Research Compliance Program provided written guidance and/or insight regarding the following issue areas:

- Clinical Trial Agreement/Grant Review: Collaborated with CCH Compliance, the Office of the General Counsel and representatives from the Research & Regulatory Affairs and the Center of Health Equity & Innovation to review and streamline the process for review and signature for clinical trial agreements and grants.
- Data Sharing Agreements for Research: Collaborated with CCH Compliance, the Office of the General Counsel and Information Security to better understand review processes for data sharing, including the review of agreements and/or contracts that impact CCH PHI.
- Federal Contracting Requirement Review: Collaborated with CCH Compliance, the Office of the General Counsel and Internal Audit to review and outline the applicability of the NIH Grants Management Policy and the Federal Acquisition Regulation (FAR) to research conducted at CCH.
- Signature Authority for Certifications and Reliance documents: Researched and provided guidance on ability for research department lead to approve and execute sign off on Extramural Institutional Certifications and IRB Reliance Agreements.

Element 2

The designation of a compliance officer and a compliance committee that are responsible for developing, operating, and monitoring the compliance program, and with authority to report directly to the head of the organization.

CCH Compliance Program Oversight

The graphic here illustrates the communication and reporting structure for CCH Compliance, of which the Research Compliance Program is embedded within.

Nicole Almiro, the Chief Compliance & Privacy Officer, reports to the CCH Audit & Compliance Committee of the Board and the CCH Chief Executive Officer. In turn, the CCH Audit & Compliance Committee of the Board and the CCH Chief Executive Officer each report to the CCH Board of Directors.

The **Audit & Compliance Committee of the Board** advises the CCH Board of Directors regarding the implementation of standards and processes to assure professional responsibility and honest behavior, compliance with regulatory requirements, and risk management.

The interim Research Compliance Officer reports to the Chief Compliance & Privacy Officer and is responsible for the development, oversight and monitoring of the Research Compliance Program, which is supported by the CCH Compliance program.

The primary duties of the **Interim Research Compliance Officer** include the following:

- Overseeing the Research Compliance Program interpreting and applying regulatory laws and guidance governing research, including financial and non-financial regulations.
- Coordinating and administratively leading the Research Compliance Committee meetings and serving on any Research related committees, including ad-hoc committees.
- Serving as CCH's subject matter expert for regulations and guidelines governing research, including, but not limited to, the Uniform Guidance, National Institutes of Health Grants Policy Statement, and regulations governing research conflicts of interest, human research protections, environmental health & safety, export controls, clinical research billing, and research misconduct.
- Keeping current on new federal regulations, rules, revisions and other industry standards that govern research and demonstrating an understanding of current events that influence research guidelines and regulatory processes.
- Acting as a resource for research compliance-related inquiries and policy clarification.
- Maintaining open lines of communication with other departments including the Office of Research & Regulatory Affairs, Center for Health Equity and Innovation, the CCH IRB and CCH Compliance.
- Implementing policies and procedures that govern the Research Compliance Program.
- Developing, implementing and overseeing institutional research-related compliance policies, procedures, guidelines and programs that enable the conduct of research while ensuring compliance with regulatory requirements.
- Collaborating with business units to define roles and responsibilities for research compliance-related activities, including activities of the research compliance program and operational responsibilities of business units.
- Overseeing internal investigations into research-related compliance issues and coordinates investigations.
- Collaborating with key CCH/Research Institute leadership, employees, and physicians to identify, research, investigate and resolve research-related compliance issues.
- Partnering with business units to ensure corrective action resulting from investigations is taken, including disciplinary action as applicable.
- Tracking and trending research compliance-related allegations, investigations, and outcomes.
- Collaborating with CCH Compliance and Office of General Counsel and escalates issues to CCH leadership as appropriate, when investigating issues that may violate criminal law and/or require reporting to government bodies.
- Providing communication and training to the CCH community on research compliance-related matters.

- Developing, coordinating, and participating in an educational training program that ensures compliance with pertinent policies and federal and state standards and augments training and communication for high-risk areas, including, but not limited to, research misconduct, conflicts of interest, foreign influence, etc.
- Overseeing response to and communicating new regulatory changes to affected departments/individuals by assembling work groups and developing/providing education and training.
- In collaboration with CCH Compliance, conducting a risk assessment to proactively identify areas of research-related risk for CCH.
- Developing and managing an annual Research Compliance Work Plan based off the risk assessment to reduce organizational risk.
- Ensuring that the program is structured to prevent, detect, and equitably resolve research compliance issues.
- Participating in projects related to processes or systems that further promote an effective Research Compliance Program.

In addition to the aforementioned relationships, the Research Compliance Officer receives support and guidance from the internal **Research Compliance Committee**, an assembly of executive leaders within CCH who meet on a quarterly basis, including but not limited to, the CEO, Chief Medical Officer, the Chair of the CCH IRB, the Chief Equity and Inclusion Officer, the Chief Financial Officer, the Office of General Counsel, the System Director of Internal Audit, Chief Information Officer, the Director of Research & Regulatory Affairs, the Assistant Grants Management Director and CCH Principal Investigators who are currently conducting research activities on behalf of CCH. The purpose of the Research Compliance Committee is to advise and assist the CCH Research Compliance Officer in the development, implementation and oversight of CCH's Research Compliance Program.

Element 3

The development and implementation of education and training programs for all affected employees that are provided regularly and updated as necessary to be effective.

Education and Training

As has been stated before, the Research Compliance Program leverages the existing compliance education structure to ensure that all individuals performing research activities on behalf of CCH receive adequate compliance related training upon hire and on an annual basis. Subject areas related to CCH Compliance, the Code of Ethics, Fraud, Waste and Abuse (FWA) and Health Insurance Portability and Accountability Act (HIPAA) Privacy are addressed in training materials.

Additionally, Principal Investigators and their staff are required to complete human subject protection training modules as outlined in the application for research that is reviewed by the CCH IRB, which includes formal research ethics training. Ongoing efforts are underway to identify subject areas for enhanced, ad hoc education that will be developed by Research Compliance.

Element 4

The creation and maintenance of an effective line of communication between the compliance officer and all employees, that includes a process to receive complaints or questions and allows the option to report issues in a manner that protects the anonymity of complainants and protects whistleblowers from retaliation.

Receiving and Responding to Complaints

Similar to other elements already addressed, Research Compliance leveraged existing CCH Compliance mechanisms for communicating with workforce members regarding research related issues, including:

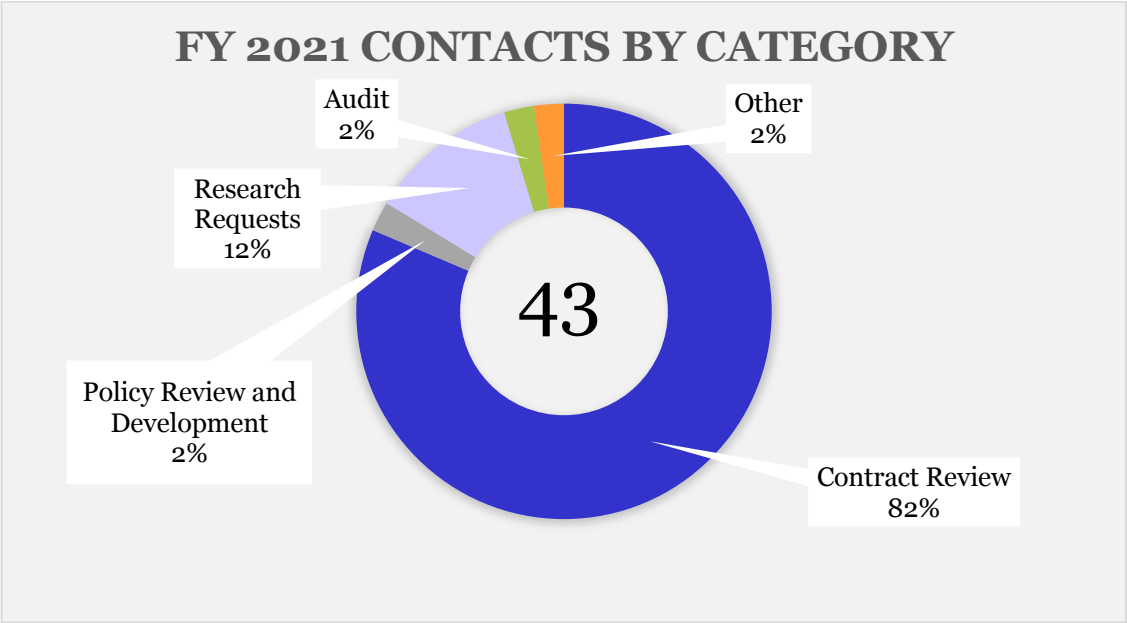
- A hotline service provided by an independent, contracted third-party to preserve caller anonymity if desired. The individual is given a code number related to their report and can call back or check the website using that code number to review comments and updates. In FY21, 51 calls or internet/online inquiries were received on the hotline.
- Maintained two email addresses for departmental notices and communications:
  - Compliance (compliance@cookcountyhhs.org) and
  - Privacy (privacy@cookcountyhhs.org).
- Collaboration with operational areas, including but not limited to General Counsel, Human Resources, HIS, Finance, CCH IRB, Research & Regulatory Affairs, and the Centers for Health Equity & Innovation to assist in resolving Research compliance-related issues.

The process for responding to compliance contacts related to Research also followed the SBAR workflow, an acronym for **S**ituation, **B**ackground, **A**ssessment, **R**ecommendation, which is identical to that as followed by CCH Compliance and CountyCare Compliance.

The diagram included here illustrates the approach to incident investigation and ensures that all the causes are discerned and addressed by appropriate actions, including detection, reporting and correction of inappropriate actions, as well as monitoring for issues post mitigation.

Research Contact Volume for FY 2021

In its first year of operation in FY 2021, 43 identified contacts were received and documented for the CCH Research Compliance Program.



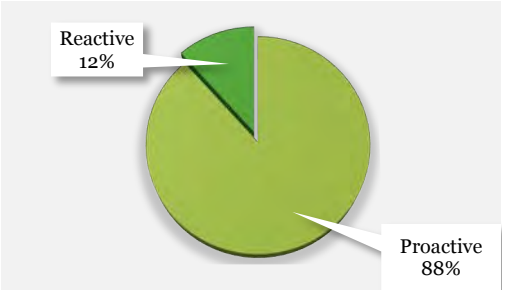
Contacts related to research included requests for the below listed activities:

Categories	Count
Review of contracts or agreements related to research (including clinical trial agreements, study contracts, grants, non-disclosure agreements, data transfer and/or sharing agreements, etc.)	35
Research or regulatory review requests	5
Policy review and / or development	1
Audits	1
Other	1

FY 2021 Proactive vs. Reactive

It has been a longstanding goal of CCH Compliance to balance to the number of proactive versus reactive contacts that come into the department.

Of the 43 Research compliance contacts managed during FY 2021, 5 contacts or 12% were reactive. Reactive contacts occur in response to an action that has already been initiated. On the proactive side, 88% or 38 contacts were classified as proactive. The proactive category is defined as questions brought to the attention of Research Compliance by individuals seeking guidance prior to the occurrence of an event or activity.



Compliance continues to be encouraged by the positive trend towards individuals seeking guidance prior to embarking upon an action.

Element 5

The development of policies and procedures to investigate identified instances of non-compliance or misconduct and implementing a prompt and proper response to detected offenses through the initiation of appropriate corrective action and preventive measures.

Enforcing Standards

The Research Compliance Program leverages existing CCH policies and standards of enforcement for its activities to ensure that prompt and proper response to detected offenses is taken through the initiation of appropriate corrective action and preventive measures, in close collaboration with the Human Resources department.

In its inaugural year of operations, Research Compliance relied upon the following standards of enforcement, in collaboration with the CCH Privacy Officer and Compliance department:

- Breach Assessments. Reviewed investigations and provided remediation guidance to the Research department to minimize and/or eliminate breaches in the future and utilized the CCH Sanction Policy and Personnel Rules, to provide leadership guidance for disciplinary action. Where necessary, the Privacy Officer completes breach notification requirements for confirmed HIPAA breaches. A breach occurs where there is an impermissible access to, use, or disclosure of research participant PHI. Notification involves drafting a letter to each impacted participant, explaining what happened, what information was compromised, and what CCH is doing to mitigate further harm. Research Compliance received one (1) report of a potential HIPAA breach in FY 2021. This occurred when a researcher used the "CC" line instead of the "BCC" line to send a communication to research participants, thereby allowing participants to see each other's phone numbers. In total, 112 participants were impacted.

- Breach Notification. Investigated all instances of lost or stolen PHI, including paper and electronic. For all instances in which the data loss constitutes a breach as defined by the Breach Notification Rule, the breach notification requirements to the patient, the Secretary of HHS, and the media are completed. Corrective action plans are

created and executed to improve the processes and counsel the physicians and employees involved.

Element 6

The use of audits and/or other techniques to evaluate risks to monitor compliance and identify problem areas

Risk Assessment

As part of the initial implementation of the Research Compliance Program, an informal risk assessment was conducted that focused on key risk areas for research, as observed nationally and as identified internally at CCH. The following focus areas were identified in FY 2021:

- Financial Conflict of Interests
- Accurate Billing for Research
- Processes in Place for Legal/Compliance Study Review and Approval
- Privacy/Security Concerns for Information Sharing
- Potential Research Misconduct (plagiarism, fabrication, and falsification)
- Allocation of Research/Grant Funding
- Informed Consent Management

Efforts are currently underway to document and finalize the Risk Assessment process. Formal documentation will be available in FY 2022.

Auditing and Monitoring

Research Compliance initiated two audits during FY 2021, as described below:

- Discovery audit of the existing research compliance billing process for a randomly selected study, designed to learn more about how services related to clinical studies are billed for at the study and organization level at CCH; and
- Initiation of a CMS Open Payments audit, including the review of conflict-of-interest information for CCH personnel (including those involved in research studies) against publicly available information on the CMS Open Payments website.

Notably, no external audits were conducted during FY 2021 related to research activities by government regulators or third-party sponsors.

As the Research Compliance Program was newly developed, a formal auditing and monitoring plan has yet to be developed. Upon completion of the Risk Assessment, a formal auditing and monitoring plan will be developed based on the project outcome.

Element 7

The enforcement of appropriate disciplinary action against employees or contractors who have violated Federal requirements and/or institutional policies and procedures in relation to the use of Federal research dollars.

The Research Compliance Program leverages existing CCH policies and disciplinary processes for its activities, in close collaboration with the Human Resources department. Notably, the following sanction screening check procedures apply to all individuals conducting research activities at CCH:

Sanction Screening Checks

- A policy and procedure paralleling the requirements set forth by the Department of Health and Human Services, Office of Inspector General, is in place to ensure the screening of all contractors and workforce members.
- The policy is placed to avoid employing, engaging, contracting or agreeing with any individual or entity that is excluded or "sanctioned" from participation in a federal health care program or who is debarred from participation in federal procurement or non-procurement programs for the provision of goods or services.
- CCH screens all employees prior to hire and vendors prior to contracting.
- Delegated vendors attest to screening of all workforce members upon hire and routinely thereafter.
- CCH Compliance, through an independent third party, is responsible for subsequent screenings. The third-party screens workforce members, employees of delegated vendors that work at CCH locations or have contact with a patient or CountyCare member, monthly and annually.

No excluded or sanctioned workforce members or vendors who conduct research at CCH were identified throughout this fiscal year.

Element 8

The clear definition of roles and responsibilities within the institution's organization and ensuring that oversight responsibilities are effectively assigned

As part of the Risk Assessment process outlined above, Research Compliance actively gathered information related to the volume and types of research and grant funded activities conducted by various CCH departments, including the Research & Regulatory Affairs department, the Center for Health Equity & Innovation and the Finance department. In the coming year, Research

Compliance will continue to collaborate with key stakeholders to help build out more formal research office functionalities, including a structure for appropriate oversight.

V. Looking Ahead to 2022

In FY 2022, Research Compliance plans to continue collaborating with the various departments conducting research at CCH to assess potential risk areas, identify areas of potential non-compliance and work toward strengthening and improving research compliance at CCH.

Other notable priorities for FY 2022 include:

- Continued Implementation of the Research Compliance Program: As the Research Compliance Program was newly initiated in FY 2021, many initiatives to strengthen the program will continue in FY 2022, including identification of a permanent CCH Research Compliance Officer.
- Financial Conflict of Interest audit: Completion of the CMS Open Payments audit and identification of areas for improvement related to existing disclosures processes.
- Audit Collaboration: In collaboration with the CCH Research & Regulatory Affairs department, review the current schedule of audits conducted and determine where Research Compliance may be leveraged for support for internal and external audit activities.
- Focused Review of Clinical Trial Billing Processes: Review and identify areas of improvement related to uniform clinical trial billing processes at CCH, including how CCH patients may be flagged as participating in a research study within the electronic medical record and whether enhanced bill review processes are needed for charges related to research studies.
- Policy Development: Continued development of the Federal Contracting policy and Financial Conflicts of Interest policy, as well as other policies deemed necessary based on the finalization of the Risk Assessment and upon request from CCH operations.
- Compliance Education: Development compliance training materials specific to research compliance, including materials around Financial Conflicts of Interest and newly implemented processes.
- Formalization of the CCH Research Office: Continued collaboration with departments involved in research activities to formalize research office functionalities and responsibilities, including potential identification of a solution for managing and tracking clinical trial activities.
- Regulatory Changes: Ongoing monitoring of regulatory changes impacting Research Compliance.