



COOK COUNTY
HEALTH

Cook County Health System Compliance Program

Annual Report
Fiscal Year 2022
December 1, 2021 – November 30, 2022

January 20, 2023

Table of Contents

I.	Executive Summary.....	3
II.	Introduction	5
III.	Building Blocks – Program Infrastructure and Scope.....	6
IV.	Being Present – Communication – Fostering Transparency.....	7
V.	Annual Compliance Program Structures - Performance of the Elements.....	8
	Element 1 - Standards of Conduct, Policies and Procedures.....	8
	Element 2 - Compliance Office and Oversight Responsibilities.....	10
	Element 3 - Education and Training.....	12
	Element 4 - Receiving and Responding to Complaints.....	13
	Element 5 - Enforcing Standards.....	18
	Element 6 - Monitoring and Auditing.....	19
	Element 7 - Prevention.....	21
VI.	Looking Ahead to 2023.....	21

Cook County Health
Compliance Program
ANNUAL REPORT – FY2022

I. Executive Summary

The Fiscal Year (FY) 2022 Compliance Program Annual Report summarizes the primary compliance activities that the Cook County Health (CCH) System Compliance Program (CCH Compliance Program) accomplished in FY 2022 and identifies priorities for FY 2023.

During this past fiscal year, the CCH Compliance Program achieved many of its stated goals, implemented many new initiatives despite reduced staffing levels in the department, and established plans to expand on this progress in FY2023. Notable activities include:

- Vigorous Auditing and Monitoring: CCH Compliance undertook significant auditing and monitoring efforts in FY22, which will be detailed throughout this report. Subject areas for auditing and monitoring included: research billing; employee badging; teaching physician requirements; medical record documentation; Medicare’s provider-based department rules; billing based on level of care; and compliance with information blocking regulations.
- Committee Participation: CCH Compliance increased its presence throughout the health system by serving on a number of committees, including: utilization management; clinical documentation; 340B; research compliance; Information Blocking; data governance; Health Information Systems (HIS) clinical advisory; registration process; Serious Events Review Team (SERT) meeting; and patient portal planning.
- Expanding Education Efforts: Expanded education efforts across a number of topics including: fraud, waste, and abuse; information blocking; Compliance in the News; compliance week news blasts to the entire organization; board member fiscal responsibility; and dual employment.
- Compliance Policy Updates: Made significant updates and improvements to most of the Compliance policies, including Health Insurance Portability and Accountability Act (HIPAA) policies; auditing and monitoring; fraud, waste, and abuse; dual employment; and conflict of interest. Compliance also introduced new policies on the following topics: federal contracting for research studies and grants; financial conflict of interest (FCOI); teaching physician requirements; non-retaliation; and began drafting a new gifts policy. Also, Compliance continued reviewer and approver responsibilities on policies from other departments such as Registration, Human Resources, Health Information Management (HIM), and HIS.
- Accessibility: On an ongoing basis, CCH Compliance continues to respond to inquiries, allegations, and complaints in addition to monitoring these contacts for patterns and trends.
- Dual Employment Survey: Administered the FY 2022 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.

Cook County Health
Compliance Program
ANNUAL REPORT – FY2022

In FY 2023, CCH Compliance will continue serving as a trusted and reliable resource for all workforce members within CCH, as well as CCH patients, CountyCare members, vendors, and the 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 2023 include:

- Expanded Compliance Education: Given the ever-changing healthcare regulatory environment, there is a need to update policies and processes and communicate these changes quickly to employees in a manner that is easily understood and retained. Further, it is necessary to educate workforce members on areas of established law or policy when audit results show room for improvement. CCH Compliance made strides toward increased education in FY22 but plans to continue these efforts in FY23. These efforts include plans to revamp New Employee Orientation and Annual Training as well as targeted education to clinical departments.
- Research Compliance Program: Continued development of the 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. CCH Compliance is teaming with HIS to establish a flag in the electronic medical record for CCH patients participating in a research study. A Clinical Trials Office is also in development to provide the needed research infrastructure.
- Clinical Documentation Education Program: Centers for Medicare & Medicaid Services (CMS) recently made landmark changes to documentation, coding, and billing for evaluation and management services. To enhance compliance with these recent changes, CCH Compliance will partner with CCH leadership to 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 Compliance-related Questions in Exit Survey: CCH Compliance intends to work with Human Resources to ensure that workforce members leaving the institution can provide feedback on any compliance issues or concerns. Based on this feedback, CCH Compliance will establish necessary corrective action to mitigate future reoccurrence.
- Implementation of More Proactive Privacy Initiatives: Continue emphasis on the importance of safeguarding Protective Health Information (PHI) as required by HIPAA while also following new information blocking rules, which seeks to enhance patient access to their medical records. CCH Compliance also plans to take proactive privacy measures, including access audits and working with HIS to ensure appropriate technical safeguards.
- Ongoing monitoring of regulatory changes.

Cook County Health
Compliance Program
ANNUAL REPORT – FY2022

II. Introduction

The CCH Compliance Program incorporates two (2) distinct Compliance Programs: one encompassing CCH as a provider of health care services and the other encompassing the CountyCare Medicaid Health Plan. Executive oversight of both programs is done by a Chief Compliance & Privacy Officer. 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 perform services on behalf of CCH and access our patients’ and members’ PHI in varying capacities to carry out their contracted services.

Although both the CountyCare Medicaid Health Plan and CCH Compliance Program are addressed through separate annual reports, both 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 established and continues to enforce 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.

This Annual Report presents the key activities throughout the county fiscal year 2022 (FY22) of the System CCH Compliance Program under the executive leadership of Nicole Almiro, Chief Compliance & Privacy Officer, with support by Ashley Huntington, Compliance Officer and interim Privacy Officer, Agnieszka Snopek and Aleksandar Mojsilovic, Compliance Analysts, and other external compliance resources to assist with critical projects and temporarily fill staffing openings. Note that in September 2022 after multiple rounds of searching, Compliance welcomed Aleksandar Mojsilovic as a Compliance Analyst.

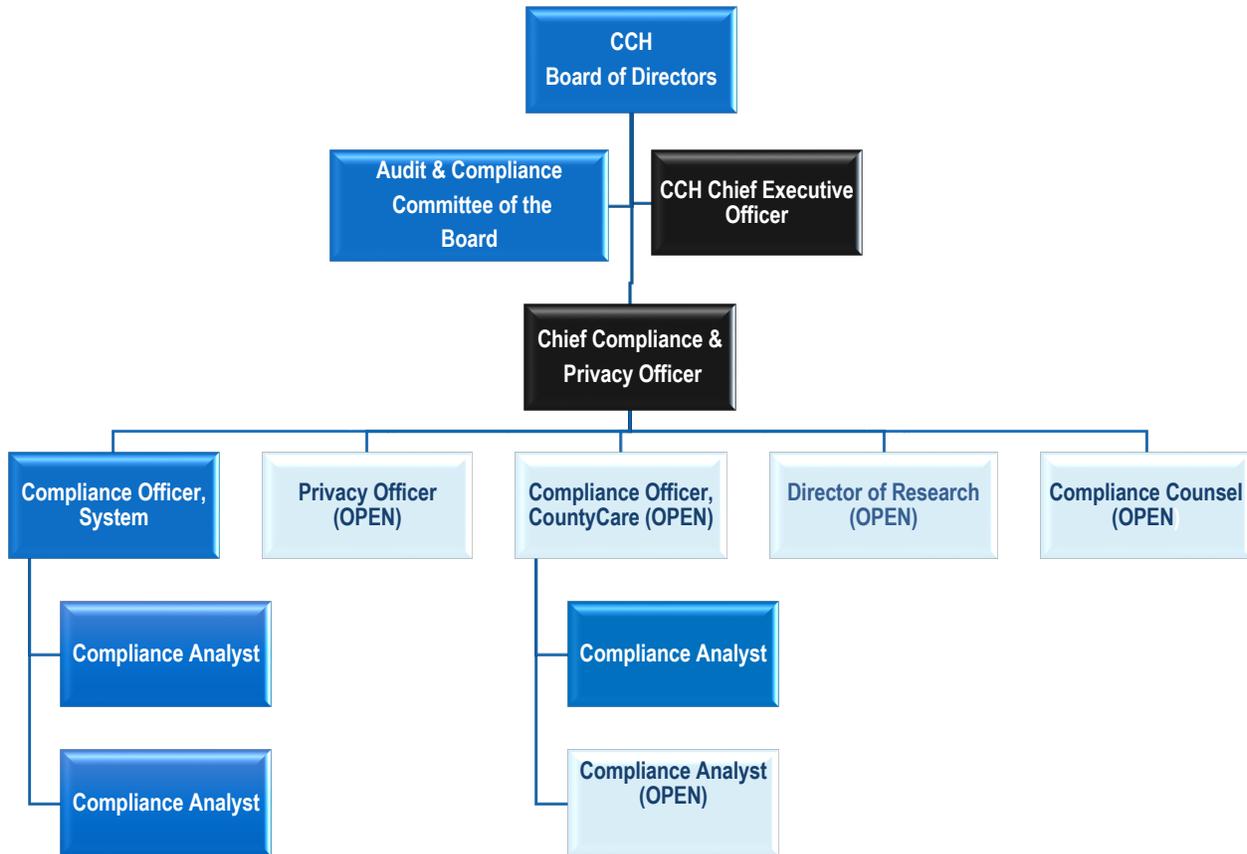
In addition, this report provides an assessment of the effectiveness of the CCH Compliance Program by examining the Program’s adherence to the seven (7) Compliance Program Elements as recommended in the Department of Health and Human Services (HHS) Office of Inspector General (OIG) Compliance Program 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.

Cook County Health
Compliance Program
 ANNUAL REPORT – FY2022

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 FY22. The Compliance Officer, supporting CountyCare operations resigned in August 2022. To fill this gap, in September 2022, CCH Compliance repurposed a longtime consultant from Strategic Management Services, acting as interim Director of Research, to CountyCare Compliance. After a lengthy search and interview process, Aleksandar Mojsilovic was hired in September 2022, filling one of the open Compliance Analyst roles.

Nevertheless, due to the significant staffing shortages, CCH Compliance continued its interdepartmental workload redistribution with additional workload in Research Compliance and Contracts review.

CCH Compliance Program Scope

CCH Compliance continued to serve as a subject matter expert in many areas in FY22. Activities that fall into the CCH Compliance purview include:

Cook County Health
Compliance Program
ANNUAL REPORT – FY2022

- 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;
- Review of documentation pertaining to Additional Development Requests (ADR) from National Government Services, Inc. and coordinating education with affected departments to ensure improvement;
- Assessment and reassessment of CCH Compliance policies and procedures, including updates due to time and/or regulatory changes;
- 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; and
- Safeguard privacy, confidentiality, and security of PHI under HIPAA and related federal and state privacy and confidentiality laws.

IV. Being Present – Communication – Fostering Transparency

Communication Strategy

CCH Compliance continued its goal of establishing and maintaining visibility and accessibility to CCH workforce, patients, and members, where appropriate. Compliance found ways to work around having a more remote or hybrid workforce by utilizing virtual meetings and trainings. Where appropriate and during times of low transmission of COVID-19 and other viruses, Compliance facilitated in-person trainings and webinar viewings. Compliance has also had staff physically present in the office for the entirety of FY22, allowing for workforce members to drop by and request guidance or assistance. Although in-person training has decreased significantly over the last few years due to safety issues with gathering groups of people together, CCH Compliance used virtual tools to bring workforce awareness of the following topics:

- Accessibility of the System CCH Compliance and Privacy teams;
- Fraud, Waste, & Abuse;
- Compliance with the Code of Ethics;
- Responsibilities regarding privacy, confidentiality, and security of PHI;
- Requirements to report potential/actual Compliance-related issues;
- Dual employment reminders;
- Conflict of interest guidance; and
- Zero-tolerance for retaliation.

Communication Channels

As with prior years, CCH Compliance used many modalities to communicate the aforementioned topics including:

- Email communications, particularly to the CCH workforce members requesting guidance on an array of topics including, but not limited to, rules on sharing PHI inside and outside the institution, federal grant requirements, and evaluation of potential conflicts of interest.
- New employee orientation. In FY22, Compliance resumed participating in and presenting at orientation in-person.
- Annual education for all CCH workforce on compliance topics including the CCH Code of Ethics, Privacy, and Fraud, Waste & Abuse. Compliance intends to revise all annual education in FY23.
- Increased presence at team meetings and serving on a number of committees to advance compliance initiatives and visibility of department.

V. 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 workforce members, including providers, agents, and subcontractors. The Code of Ethics, as well as CCH's policies and procedures, support the organization's commitment to compliance with all federal and state standards, including but not limited to, applicable statutes, regulations, and sub-regulatory guidance. Contractual obligations are also reviewed on a regular basis.

Policies and Procedures

In FY22, Compliance devoted significant time and effort to overhauling its policies. This including an update of all HIPAA policies as well as the following: Compliance Auditing and Monitoring; Fraud, Waste, and Abuse; Dual Employment; and Conflict of Interest. Compliance also developed several new policies to fill needed gaps. These policies include Federal contracting for Research Studies and Grants, FCOI, Teaching Physician Requirements, Non-Retaliation, and a new Gifts policy is in development. The effort to update and add policies is ongoing and will continue into FY23 with planned policy additions in the areas of Information Blocking, Transportation, and the Food Bank. As with prior years, Compliance served as a primary reviewer and approver for numerous organizational policies with compliance, privacy, and/or security elements and provided regulatory guidance and leadership to ensure uniformity throughout policies across 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:

- Provided significant review and guidance when approached with increased requests to share CCH PHI. These requests come from several community partners, other healthcare facilities, and vendors. Each request is weighed on a case-by-case basis to determine the appropriateness of the data being requested and what can be shared in compliance with strict Federal and state regulations.
 - 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 and into FY22, 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.
 - CCH Compliance has also partnered with Business Intelligence to serve on a data governance committee, which evaluates these requests and establishes processes for handling them.
- Continued efforts toward building Research Compliance Program and Research Compliance Committee.
 - Continued working with longtime Compliance consultants, Strategic Management, to develop research compliance oversight processes.
 - 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.

Cook County Health
Compliance Program
ANNUAL REPORT – FY2022

- Undertook significant auditing and monitoring activities.
 - CCH Compliance increased its auditing and monitoring activities substantially, especially regarding the revenue cycle process at CCH and CMS Teaching Physician requirements and other areas detailed above.
- Significantly increased review of contracts and agreements as part of executive leadership’s new process.
 - As reflected in the metrics below, contracts and agreements now account for approximately 50% of the contact types coming into the department.
- Audited CCH badging process for compliance with both CCH policies and procedures as well as Illinois state law.
- 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. Future goal is to make content easier to understand and retain with short-form, educational video instruction.
- Facilitated Annual Dual Employment Survey.
 - 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.
 - Increased support from executive leadership to ensure that all surveys completed timely, and that managers and supervisors conduct appropriate review before approval of surveys.
 - Planned review of reported Dual Employment data in FY23.

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.

Compliance Office and Committees

The graphic that follows illustrates the communication and reporting structure. Nicole Almiro, 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.

Cook County Health
Compliance Program
ANNUAL REPORT – FY2022



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.

Cook County Health
Compliance Program
ANNUAL REPORT – FY2022

- 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.

Element 3

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

Education and Training

1. New Employee Orientation

CCH Compliance continued its attendance and presentation at New Employee Orientation once every two weeks to present an “Introduction to CCH Compliance and HIPAA.” Compliance presented its materials every two weeks from that time for a total of approximately 26 presentations in FY22. Compliance is also working with Human Resources to revamp and introduce a new version of the Compliance materials at New Employee Orientation in FY23.

2. Targeted Education

Historically, 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 changing regulations and the rollout of new compliance policies to address needed topics, Compliance provided targeted education on many different topics in FY22. This included fraud, waste, and abuse, information blocking, teaching physician requirements, regulatory updates, compliance week news blast to the entire organization, board member fiscal responsibility, and dual employment education and reminders.

3. Annual Compliance Education

As noted earlier, responsible for three (3) mandatory education modules: Code of Ethics; Fraud, Waste and Abuse; and Privacy. All modules will be revised in FY23 to deliver new content and reflect regulatory updates.

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 FY22, 61 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, HIS, Patient Relations, Revenue Cycle, Research, and HIM, Registration and Scheduling, and others 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:
 - Continued oversight of CCH's compliance with right of access provisions under the HIPAA Privacy Rule.
 - CCH Compliance noted an ongoing uptick in enforcement actions by the Office for Civil Rights (OCR) related to right of access violations.

Cook County Health
Compliance Program
ANNUAL REPORT – FY2022

- Partnered with HIM and their contractor to resolve complaints from patients, attorneys, and regulators that records requests were unfulfilled or delinquent.
- Engaged contractor leadership to address repeated issues with their staff, including delinquent requests and breaches of protected health information. This included targeted education for contractor staff and an auditor performing a site visit and report to CCH.
- 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, four (4) separate Level of Care audits were conducted by CCH Compliance to determine if guidance and new report improved compliance.
- Performed a review of Medicare’s Provider-Based Department requirements and implemented required changes, including but not limited to, additional signage, patient notices, and revalidating Medicare’s online enrollment management system.
- Assisted with correction of documentation in Cerner caused by input of incorrect COVID-19 and Monkeypox vaccine lot numbers.

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

General Processes for Responding to Inquiries, Issues and Complaints

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.

Cook County Health
Compliance Program
ANNUAL REPORT – FY2022

Lastly, the Recommendation,

- 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 Assessment determines a reportable breach has occurred then,

- HIPAA breach notification rules regulatorily require sending a notification letter to the affected individual(s) within sixty (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.

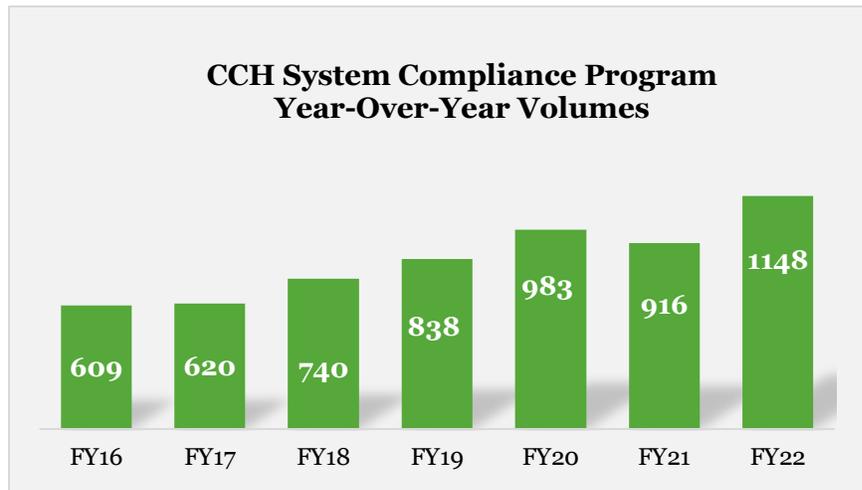
Similarly, collaboration with the operational area to determine and facilitate a corrective action plan which includes re-education.

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 FY22, 1,148 identified contacts were documented for the CCH Compliance Program. The chart that follows illustrates the year-over-year activity. CCH Compliance notes that it still maintained a high level of visibility in the organization and managed a high volume of day-to-day issues while also dedicating significant time and effort to larger scale projects, including a policy and procedure overhaul and significant auditing and monitoring activity. CCH Compliance also believes its effectiveness is not only demonstrated by an increase in contacts. Rather, CCH Compliance is encouraged that the guidance it gives allows departments to evaluate and manage similar occurrences in the future without the need for CCH 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.

FY22 categories are as follows:

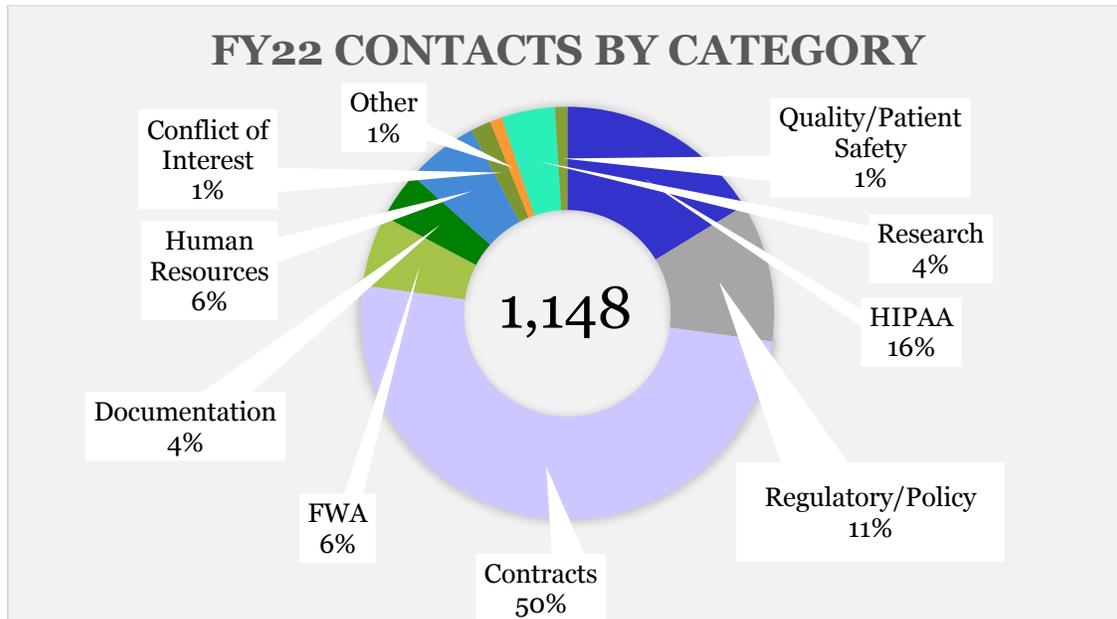
- Conflict of Interest
- Contracts/Agreements
- Documentation
- Fraud, Waste and Abuse, and Financial Misconduct
- HIPAA Privacy, Confidentiality and Security
- Human Resources
- Quality/Patient Safety
- Regulatory/Policy
- Research
- Other (Comprised of contacts that may include theft and miscellaneous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

FY22 Contacts by Category

Unlike prior years, the Contracts contact type now comprises the largest share of contacts coming into CCH Compliance at 574, or 50%. Compliance saw a massive increase in the Contracts category in FY22 which can be attributed to the new process established by senior leadership which involves having multiple levels of review and sign-off prior to the contract receiving final approval. Behind that, HIPAA Privacy, Confidentiality, and Security accounts for 187 or 16% of contacts. This shows a decrease as compared to previous years which can be attributed to the following: CCH Compliance previously reviewed research clinical trial agreements from only a

Cook County Health
Compliance Program
 ANNUAL REPORT – FY2022

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 15 HIPAA Privacy, Confidentiality, and Security contacts were confirmed privacy breaches that required notification to 113 patients. Compliance is encouraged by the decrease in breaches year over year and has noted that breaches involving prescriptions being mailed to the wrong individual have gone down substantially.



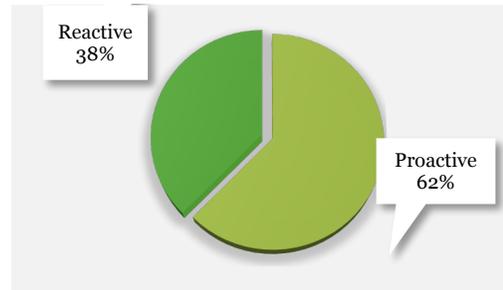
Categories	Count	Categories	Count
Contracts	574	Privacy/Security (HIPAA)	187
Regulatory/Policy	125	Human Resources	66
FWA	64	Research	48
Documentation	44	Conflict of Interest	18
Other	11	Quality/Patient Safety	11

FY22 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 contacts now exceeding reactive contacts for the first time since Compliance began tracking this specific data point.

Cook County Health
Compliance Program
ANNUAL REPORT – FY2022

Of the 1,148 System Compliance contacts managed during FY22, 716 contacts or 62% were 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. Reactive contacts occur in response to an action that has already been initiated and accounted for 432 contacts or 38%.



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

Research Compliance. As part of FY21's effort to establish a Research Compliance Program, CCH Compliance continues its efforts in FY22 by reviewing federal requirements related to receiving or participating in federal funded grants and research studies and developed the Federal Contracting and Financial Conflict of Interest Policies to demonstrate compliance with these federal requirements.

Employee Badging. CCH Compliance is currently auditing CCH badging processes for compliance with both internal policies and procedures as well as Illinois state law.

Teaching Physician Requirements. CCH Compliance reviewed provider documentation compliance with Medicare's teaching physician supervision requirements and developed a Teaching Physician Requirement policy and draft attestations.

Medical Record Documentation. CCH Compliance provided education on the risks of copied and pasted (or "cloned") medical record documentation and worked with physician leadership to disable this functionality in the electronic medical record.

Contractor Corrective Action Plan (CAP) and Re-Education. CCH Compliance noticed an increase in HIPAA breaches by our vendor that assists with releasing medical records. In response to this, CCH mandated a CAP for the contractor which included:

- Re-education on HIPAA and privacy responsibilities for all contractor staff.
- A HIPAA auditor from contractor coming onsite to CCH to evaluate contractor's performance and provide CCH Compliance with findings.
- Termination of a contractor employee who caused several breaches and replacement with a new contractor employee; and
- Ongoing monitoring and discussions with contractor compliance leadership.

Privacy Access 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 P2Sentinel, to run reports showing access to certain electronic health records; and
- Working with operational leadership and Human Resources to take appropriate disciplinary action and educate staff when inappropriate access is determined.

Information Blocking. CCH Compliance, in partnership with HIS, led efforts to comply with newly effective Information Blocking rules. This included:

Cook County Health
Compliance Program
ANNUAL REPORT – FY2022

- Establishing a weekly workgroup composed of Compliance, HIS, HIM, Registration, Finance, and others to assess and revamp current processes.
- Working with Cerner to perform an assessment of CCH’s compliance with the Information Blocking rules; and
- Continued efforts in ensuring policies and procedures appropriately updated.

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 highlights 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 auditing and monitoring activities, discussions with executive leadership and key thought leaders within the organization, overlying industry risks and reports of high priority risk areas for our regulators, and through the course of activities within prior fiscal years, the following areas were identified in FY 2022 as areas of concern:

- Using, disclosing, and safeguarding PHI, in all forms, with emphasis on data security through encryption and other available technologies, with added emphasis on compliance with the new Information Blocking rules. Compliance served as a lead on this initiative to ensure compliance with the new regulations;
- Building on the foundation set in FY21 for a review process for research throughout CCH, culminating in the creation of a Research Compliance Program and development of a process to identify research participants for research bill hold purposes.
- Detecting medical record documentation copied and pasted (or “cloned”) and working to disable this functionality.
- Educating staff on Teaching Physician requirements.
- Serving as a reviewer on policies outside of the Compliance department to ensure that policies adhere to regulations and that policies have measurable standards for departmental leadership to audit and monitor within their own departments.
- Acting as a key stakeholder in contract negotiations and review. Compliance reviews the contracts for compliance and privacy, including the review and execution of Business Associate Agreements with business partners that may have access to PHI. This responsibility significantly increased in FY22 with the implementation of the review and approval process requested by the senior leadership.
- 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.

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 needed 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 monthly screenings. The third-party screens workforce members, board members, volunteers and vendors monthly.
- Determined, through an independent third party, no excluded or sanctioned CCH workforce members, board members, volunteers or vendors were identified throughout this fiscal year.

VI. Looking Ahead to 2023

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 CCH 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 public.

Cook County Health
Compliance Program
ANNUAL REPORT – FY2022

Notable priorities for FY 2023 include:

- **Compliance Education**: As part of CCH Compliance’s risk assessment, targeted education will be given to raise workforce awareness to high-risk issues. Further, the healthcare regulatory environment is ever-changing and 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 intends to use various media and modalities to reach the workforce.

- **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 focus is clinical trial billing compliance including flagging patients that are participating in a research study within the electronic medical record and the establishment of a Clinical Trial Office to review and process research claims.

- **Clinical Documentation Education Program**: CMS recently made landmark changes to documentation, coding, and billing for evaluation and management services. To enhance compliance with these recent changes, CCH Compliance will assist with developing 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, and undertaking proactive measures.