



COOK COUNTY
HEALTH

Cook County Health System Compliance Program

Annual Report

Fiscal Year 2020

December 1, 2019 – November 30, 2020

February 19, 2021

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I. Executive Summary

The Fiscal Year (FY) 2020 Compliance Program Annual Report summarizes the primary compliance activities that the Cook County Health (CCH) System Corporate Compliance Program accomplished in FY 2020 and identifies priorities for FY 2021.

During this past fiscal year, the CCH Corporate Compliance Program accomplished various goals and implemented new initiatives despite a number of hardships including the effects of the COVID-19 Public Health Emergency (PHE) and staffing levels in the department. These achievements include:

- COVID-19 Public Health Emergency: Ongoing 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.
- HIPAA Privacy Expertise: Establishing a national presence as subject matter experts in the realm of privacy compliance by presenting at multiple conferences, panels, and podcasts.
- 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: Incorporating Compliance into the multi-disciplinary team responsible for policy evaluations.
- Accessibility: On an ongoing basis, Compliance continues to respond to inquiries, allegations, and complaints in addition to monitoring these contacts for patterns and trends.
- Consultation: Providing ongoing compliance review and guidance as a member of several multi-disciplinary Task Forces and Committees.
- Dual Employment Survey: Administering the FY 2020 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 2021, Corporate Compliance plans to continue serving as a resource for all workforce members within CCH. The department will collaborate with internal partners to assess the various risk areas and areas of potential non-compliance and work toward improving those areas.

Notable priorities for FY 2021 include:

- CCH Compliance Program Evaluation: Facilitating an external, independent effectiveness evaluation of the Compliance Program. Both the Department of Justice (DOJ) and HHS Office of Inspector (OIG) call for periodic assessments of compliance program effectiveness, stressing Programs should not remain static but continue to evolve and improve over time in response to the ever changing legal and regulatory environment.

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Therefore, a key objective of the review will be to both verify and document strengths in the Compliance Program, but also seek opportunities where improvements and enhancements can be made.

- Research Compliance Program: Research is a heavily regulated environment, 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, corrects deficiencies, and assist in preventing future problems.
- Coding Integrity Program: Accurate representation of a patient's clinical status is translated into coded data. These clinical codes have a systemic impact to the revenue cycle, organizational decision-making, clinical protocols, research outcomes and external reporting. The implementation of a Coding Integrity Program within Compliance adds additional structured oversight to monitor accuracy, facilitate improvements and strengthen reporting.
- Compliance Education: Refresh, renew, and rethink all compliance training materials including new employee orientation, annual education, and ad hoc refresher training.
- Ongoing monitoring of regulatory changes.

II. Introduction

Cook County Health (CCH) System Corporate Compliance Program incorporates two (2) distinct Compliance Programs: encompassing CCH as a provider of health care services in addition to the public health department and the CountyCare Medicaid Health Plan with executive oversight of both programs 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, 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, Corporate 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 in varying capacities.

Although the CountyCare Medicaid Health Plan's Compliance Program is addressed through a separate annual report, 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. Corporate 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 activities throughout the county fiscal year 2020 (FY 2020) of the System Corporate Compliance Program under the executive leadership of Cathy Bodnar, Chief

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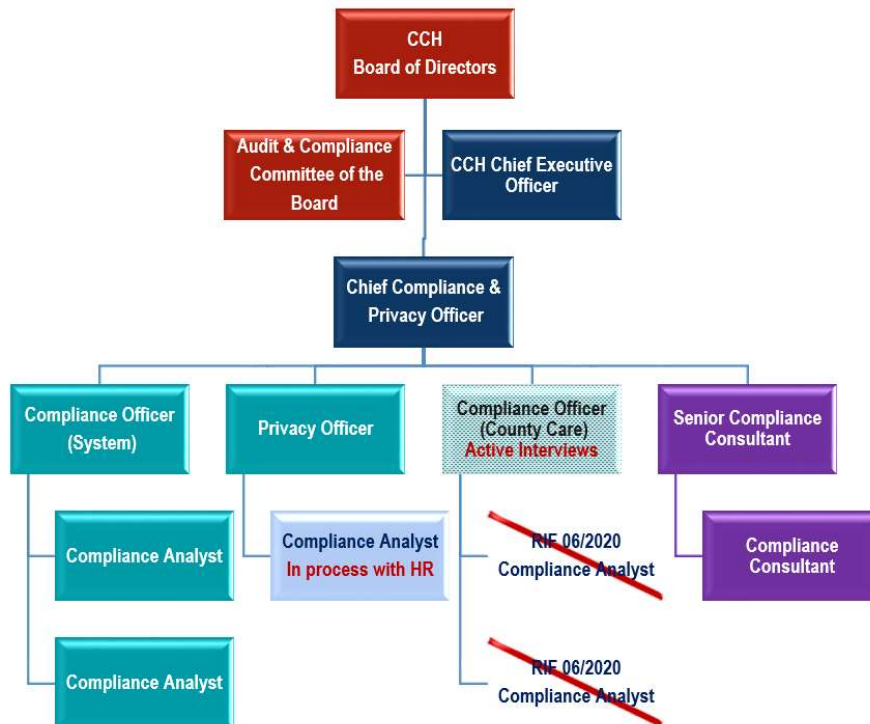
Compliance & Privacy Officer, with support by Dianne Willard, Compliance Officer, Ashley Huntington, Privacy Officer, Compliance Analysts and other external compliance resources to assist with critical projects and temporarily fill staffing openings.

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 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, 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 incorporate efforts to foster an infrastructure that produces a comprehensive compliance program. The existing Departmental Organization Chart follows:

Compliance Organizational Chart



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CCH Corporate Compliance experienced staffing shortages in FY 2020. The Compliance Officer supporting CountyCare operations resigned in February 2020. This position remains open, with a first round of interviews occurring at the end of FY 2020. A second round of interviews with a new pool of candidates is scheduled to begin in early FY 2021. Additionally, due to the CCH budget staff reduction, the department was required to eliminate two Compliance Analysts who worked on the CountyCare Compliance team. The department lost a third Compliance Analyst, who worked under the Privacy Officer, to resignation in November 2020. This position remains open.

Due to the significant staffing shortages described above, Corporate Compliance engaged in interdepartmental workload redistribution, with emphasis on CountyCare Compliance issues being redistributed to the CCH Compliance team. The department also engaged longtime department consultants, Strategic Management, LLC to assist with critical CountyCare and Privacy projects and support the overall success of CCH Corporate Compliance.

Corporate Compliance once again partnered with the Department of Human Resources to offer internship opportunities for masters-level and law school students. Corporate Compliance welcomed two interns during FY 2020. One, a Masters-level student from Governors State University, worked with the Compliance Officer. This student engaged in compliance issues and projects including: compliance oversight of the registration process, new COVID-19 coding regulations and guidance for family planning based on regulatory changes. The second student was a law student from Loyola University Chicago School of Law. This student spent time working with the Privacy Officer on issues related to: privacy breaches, privacy requirements for mental health information and substance use information, reviewing system level contracts for privacy concerns, and how to implement effective privacy training.

Corporate Compliance Program Scope

Corporate Compliance continued to serve as a subject matter expert in many areas in FY 2020. CCH activities that fall into the Corporate Compliance purview include:

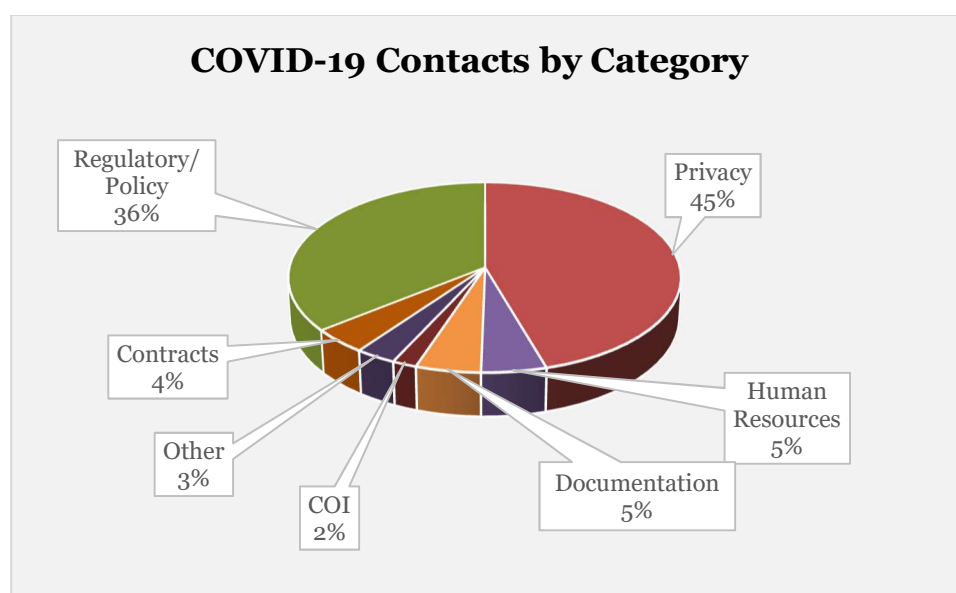
- Interpretation of federal, state, and local laws, rules, and regulations;
- Creation and maintenance of the CCH Code of Ethics along with Corporate Compliance policies and procedures;
- Investigation of allegations of inaccurate books and records including but not limited to merged medical records;
- Evaluation and guidance on potential conflicts of interest;
- Review of certain contracts/agreements, including business associate agreements, data use agreements, research, clinical trials, and grants, and compliance provisions of master service agreements;
- Assessment of compliance and policy guidance for the Emergency Medical Treatment and Labor Act (EMTALA);
- Watchdog for Fraud, Waste, Abuse and Financial Misconduct;
- Identification of risk through auditing and monitoring;
- Monitor for integrity in marketing and purchasing practices; and
- Safeguard privacy, confidentiality, and security under the Health Insurance Portability and Accountability Act (HIPAA) and related privacy and confidentiality laws.

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IV. COVID-19 Public Health Emergency (PHE) Related Activities

The story of FY 2020 would not be complete without discussing the COVID-19 PHE. As with countless other departments, CCH Corporate Compliance experienced significant impacts due to the emergence of COVID-19 – both in changing its own operations to allow for the flexibility of off-site work and in serving as a primary resource for the health system to monitor, interpret, and provide guidance on a rapidly changing regulatory landscape. Because of these adjustments, the department rose to the challenge of finding new, effective ways of being present for the organization.

Corporate Compliance received its first COVID-19 related contact on March 12, 2020. Since that time, the department responded to a total of 165 unique contacts related to COVID-19. A breakdown of the categories where COVID-19 related inquiries follows



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, Corporate Compliance received 75 unique contacts related to both COVID-19 and HIPAA. This accounts for 45% of the total contacts received by the department. Of these contacts, many related to the ways in which protected health information (PHI) can be used and shared during the pandemic.

Corporate Compliance provided guidance on the following essential topics:

- Privacy and security considerations and requirements when
 - conducting telehealth appointments;
 - using iPads to conduct virtual visits with end of life COVID-19 patients and their family members while in person visitation was temporarily prohibited;

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- sharing the PHI of COVID-19 patients with mayors, first responders, public defenders, media, and many others and whether such sharing is allowed under applicable regulations;
 - communicating rules surrounding de-identification of data to allow sharing of COVID-19 related statistics;
 - advising on privacy requirements of mobile and community-based testing sites; and
 - COVID-19 related clinical research agreements involving the use, disclosure, storage, and transmission of research subjects' PHI.
- Regulatory/Policy inquiries presented regarding
 - ongoing regulatory changes for coding/billing telehealth and telephone services;
 - 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.

Compliance anticipates providing support on COVID-19 related issues well into FY 2021.

V. Being Present – Communication – Fostering Transparency
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Communication Strategy

As with previous years, Corporate Compliance worked toward its goal of establishing and maintaining visibility and accessibility to CCH workforce although a majority of the year occurred off-site for most patient support staff. The organizational compliance communication strategy has been to increase the CCH workforce awareness of the following topics:

- Accessibility of the Corporate Compliance and Privacy team;
- Availability through multiple modalities (in-person, e-mail, phone, hot line; electronic meetings);
- Compliance with the Code of Ethics;
- Responsibilities regarding Privacy, Confidentiality, and Security;
- Requirements to report potential/actual issues; and
- Zero-tolerance for retaliation.

With the emergence of COVID-19, Corporate Compliance also spent considerable time dedicated to increase the CCH workforce's awareness of heightened privacy and security requirements, particularly during a time when the media, governmental bodies, and general public were seeking any and all information on the PHE.

Communication Channels

Within FY 2020, Corporate Compliance communicated the aforementioned topics utilizing multiple formats:

- E-mail communications, particularly to the Command Center to provide essential regulatory updates and guidance for CCH workforce;
- Organizational newsletters (System Briefs);
- New employee orientation – previously attended in person; however, in response to COVID-19, slides on Corporate Compliance, Confidentiality and Privacy (HIPAA) were developed by Compliance but presented by Human Resources;
- Annual education;
- Screen savers; and
- Attendance/presence at team meetings, serving on a number of committees and commencing 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 HIPAA as system-wide policies moved to a new software platform. Functioned as a reviewer for numerous organizational policies with compliance, privacy, and/or security elements.

As a key stakeholder on the CCH Policy Review Committee, Compliance provided regulatory guidance and leadership to ensure policies were uniform throughout the organization. In FY 2020, Compliance reviewed 165 system-wide policies through the Policy Review Committee.

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Work Plan Activities

In addition to policy and procedure activity, Corporate Compliance worked with several operational areas to assess compliance with regulatory requirements and procedures to provide guidance on steps to move forward toward meeting each requirement. Below is an overview of notable activities:

- Developed and facilitated a multi-departmental workgroup entitled, “Avoiding Tangled Records Task Force”
 - This task force was created to resolve tangled medical records found while conducting investigations and monitoring activity. This also led to amending the process for registering patients. In addition, re-education occurred for merging/unmerging records, and amending Patient Access and Health Information Management policies. At the end of FY 2020 the ownership of the Task Force transitioned to CCH operations.
- 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 records¹.”
 - CCH follows an approved Application for Authority to Dispose of Local Records, known as the Record Retention Schedule. The Schedule dates back to 1985, it contains 1,237 pages with 4,395 listed records and the associated retention periods.
 - Compliance conducted an organization-wide inventory and determined records to be maintained and the duration for which they are currently maintained. 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.
 - This activity will result in an updated Record Retention Schedule for CCH.
- Partnered with the Office of General Counsel, Healthcare Information Systems (HIS), and the Office of Programmatic Services & Innovation
 - Collaborated with the aforementioned departments to establish a review and approval process for clinical research at CCH. This partnership included weekly status updates, review of clinical trial agreements, meetings with study sponsors,

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>

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and guidance to researchers on system compliance requirements for conducting research.

- This partnership was especially important throughout COVID-19 as a number of COVID related studies were presented for review. Compliance reviewed 14 unique studies related to COVID-19.
- Trained and Educated through the online Learning Management 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 whether or not the employee engages in any outside activity.
 - The application requires attestations by each employee for compliance with the Dual Employment policy and the Conflict of Interest policy.
 - This is the second year utilizing the existing CCH Salesforce software application.

Element 2

The designation of a Chief Compliance Officer and other appropriate bodies, e.g., a corporate 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. Cathy Bodnar, 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.



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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 Corporate 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 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.

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- 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 **Corporate 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, Corporate Compliance attended New Employee Orientation once every two weeks to present an “Introduction to Corporate Compliance and HIPAA. In response to the PHE, the Department of Human Resources requested departments develop material to address their respective areas. Corporate Compliance developed a presentation to address the subject matter routinely presented, Human Resources presents the material.

2. **Targeted Education**

Prior to the PHE, Corporate 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 Corporate Compliance found it more effective to provide guidance in written form.

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 hot line, 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 hot-line 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 FY20, 68 calls or internet/online inquiries were received on the hot-line.
 - 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, and Health Information Management (HIM) to assist in resolving compliance-related issues.
2. Maintained two e-mail addresses for departmentally,
 - Compliance (compliance@cookcountyhhs.org) and
 - Privacy (privacy@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 status as a covered provider under 42 CFR Part 2.
 - Corporate Compliance worked with key clinical and administrative staff in the Medication for Addiction Treatment (MAT) program at CCH to assess compliance with privacy and confidentiality standards under 42 CFR Part 2.
 - Assisted a multi-disciplinary team to ensure that patients are billed for the correct Level of Care.
 - Corporate 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. The Level of Care is monitored and modified based on the services provided. Compliance has provided regulatory guidance, and assistance in the revision of new report that generates the daily level of care throughout the hospital. Additionally, we have communicated the need for improved documentation of level of care within the electronic health records.

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- Collaborated with a multi-disciplinary team to create stream-lined process for Gift of Hope.
 - Provided regulatory guidance regarding documentation in electronic health record for organ donation. Assisted with implementation of a new order set that can be generated by Gift of Hope employees and worked with CCH Human Resources to modify badging and security access.
 - Provided compliance guidance and monitoring for the Sexual Assault Survivors Emergency Treatment Act (SASETA) Task Force.
 - Working with the Task Force to come into compliance with regulatory requirements for photo-documentation storage, retention, and access. In addition, provided guidance for new System-Wide Policies and Procedures.
 - Created and facilitated Avoiding Tangled Records Task Force.
 - Task force was created due to many registration errors discovered while conducting monitoring and during investigations. This task force led to creating and amending Patient Access and HIM policies to avoid tangled and merged records in the future. This also forced reeducation for many registration employees as part of the corrective action plan enforced by management.
 - Worked with HIM to create an Alias note type in the Electronic Medical Record.
 - In collaboration with HIM worked to ensure an Alias note type is created. This note allows HIM to explain any name discrepancies that may be found in patients' electronic health records due to initial registration under an alias name.
 - Partnered with various departments worked on allegations of identity theft.
 - Upon patient's receipt of a bill for services patient states one did not receive, Compliance worked together with Finance, Patient Relations, Clinic management, IT, and JSH Police to determine if the correct patient was treated and accurately billed under complainant's identity and insurance. Ensured that payback was made to the appropriate payer accordingly to CMS guidance.
5. Presented trends and patterns to the CCH Compliance Executive Committee and 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, Corporate Compliance is made aware of a **S**ituation,

- Contact is made through one or multiple modalities e.g., via direct phone call or call through the compliance hot line, e-mail, and/or in-person;
- An inquiry is made, or a concern is described;
- An individual(s), area(s) or situation is identified.

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This **B**ackground information is classified, compiled and logged in the Corporate 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,

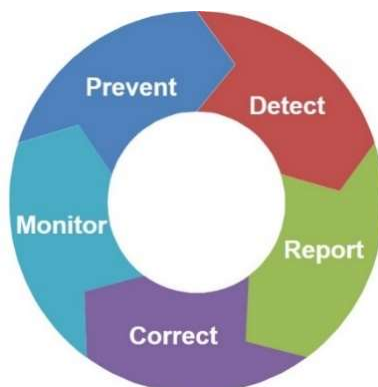
- HIPAA breach notification rules regulatorily require sending a notification letter to the affected individual(s) within sixty (60) days of discovery.
- Notification to the Office for Civil Rights (OCR) annually.

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.

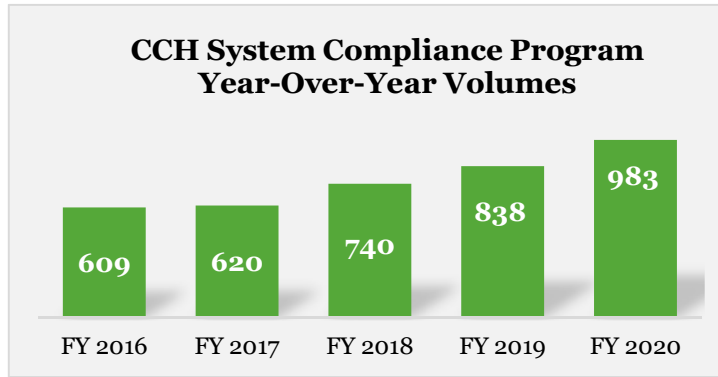
The diagram that follows illustrates the approach to incident investigation and ensures that all the causes are discerned and addressed by appropriate actions.



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Contact Volumes

In FY 2020, 983 identified contacts were documented for the CCH System Compliance Program. The chart that follows illustrates the year-over-year activity, which, despite substantial challenges from COVID-19 and staffing shortages, shows an increase of 17% compared to the previous fiscal year.



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 2020, Corporate Compliance modified its internal tracking system to include a COVID-19 check box to identify any COVID-19 related compliance issues that emerged during the pandemic. FY 2020 categories are as follows:

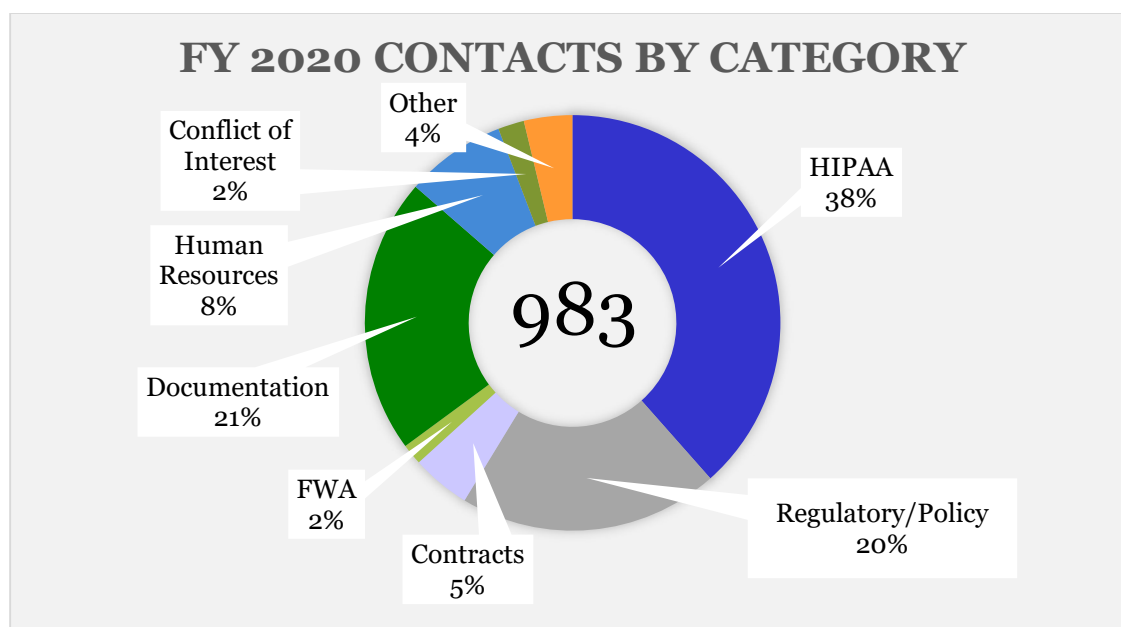
- Conflict of Interest
- Contracts/Agreements
- Documentation
- Fraud, Waste and Abuse, and Financial Misconduct
- HIPAA Privacy, Confidentiality and Security
- Human Resources
- Quality/Patient Safety
- Regulatory/Policy
- Other (Comprised of contacts that may include Research, Theft, and miscellaneous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

FY 2020 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 2020, 378 or 38%, were categorized within this category. Of the documented contacts, approximately 10% or 37 contacts were confirmed privacy breaches that required notification for 203 patients.

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It should be noted that Corporate Compliance investigated and followed reporting obligations for a breach impacting more than 500 individuals that occurred at the end of FY 2019. 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 complied the requested documentation and responded to OCR in March 2020. OCR accepted the documentation and closed the investigation in April 2020.



Categories	Count	Categories	Count
Privacy/Security (HIPAA)	378	Contracts	45
Documentation	212	Conflict of Interest	20
Regulatory/ Policy	199	FWA	16
Human Resources	77	Other	37

FY 2020 Contact Status

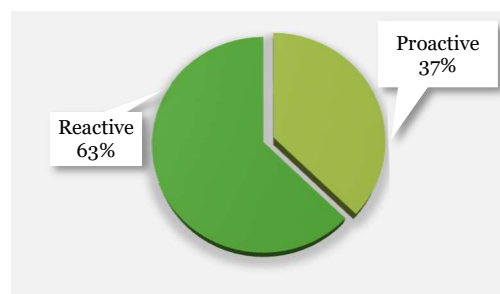
Of the 983 contacts throughout FY 2020, 96% or 947 contacts were resolved at the end of the fiscal year. The remaining contacts carried into FY 2021. Of the contacts resolved, 97% were either managed internally by Corporate Compliance or Corporate Compliance partnered with another area to address the concerns raised. This metric is consistent year-over-year.

FY 2020 Proactive vs. Reactive

It has been a longstanding goal of Corporate Compliance to restore balance to the number of proactive versus reactive contacts that come into the department. However, due to the emergence of COVID-19, efforts toward undertaking significant proactive work were halted. Further, proactive efforts cannot be successful without appropriate staffing. Due to the staffing shortages in Compliance, limited proactive work is able to be accomplished.

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Of the 983 compliance contacts managed during FY 2020, 617 contacts or 63% were reactive. Reactive contacts occur in response to an action that has already been initiated. On the proactive side, 37% or 366 contacts were classified as proactive. The proactive category is defined as questions brought to the attention of Corporate Compliance by individuals seeking guidance prior to the occurrence of an event or activity.



While not statistically significant, FY 2020 showed a 3% increase from 34% in FY 2019. Compliance is 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. Corporate 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

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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

HIPAA Auditing and Monitoring. The Privacy side of the Corporate Compliance conducted ongoing HIPAA 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;
- 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 2020 and moving forward.

Coding Audit. The Corporate Compliance Program engaged an independent third party to perform an External Professional Fee Coding Probe Audit. 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, who ensured that all claims with revenue impact were re-billed. Recognizing clinical codes have a systemic impact to the revenue cycle, as such a Corrective Action Plan was implemented. Additionally, in FY 2021, Corporate Compliance will develop a Coding Integrity Program to add additional structured oversight to monitor accuracy and facilitate improvements.

Risk Assessment

The Corporate 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, overlaying industry risks, and through the course of activities within prior fiscal years, the following areas were identified in FY 2020 as areas of concern,

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- Using, disclosing, and safeguarding PHI, in all forms, with emphasis on data security through encryption and other available technologies, was incredibly important during the COVID-19 PHE;
- Examining patient data to ensure accurate registration and deter identity theft and merged electronic health records;
- Advising Supply Chain Management during contract negotiations in the 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.

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VII. Looking Ahead to 2021

Year-Over-Year, the CCH Compliance Program continues to,

- Serve as a Corporate Compliance resource to all that require assistance throughout CCH;
- Continue to monitor regulatory changes as they relate to compliance and disseminate accordingly;
- Respond to inquiries, allegations, and complaints brought to the attention of Compliance;
- Implement solutions aimed at identifying and resolving preventable risks;
- Assess and reassess compliance and privacy policies and procedures; and
- Promote the CCH Corporate Compliance Program internally and externally.

Notable priorities for FY 2021 include:

- CCH Compliance Program Evaluation: Facilitating an external, independent effectiveness evaluation of the Compliance Program. Both the Department of Justice (DOJ) and HHS Office of Inspector General (OIG) call for periodic assessments of compliance program effectiveness, stressing Programs should not remain static but continue to evolve and improve over time in response to the ever changing legal and regulatory environment. Therefore, a key objective of the review will be to both verify and document strengths in the Compliance Program, but also seek opportunities where improvements and enhancements can be made.
- Research Compliance Program: Research is a heavily regulated environment, 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, corrects deficiencies, and assist in preventing future problems.
- Coding Integrity Program: Accurate representation of a patient's clinical status is translated into coded data. These clinical codes have a systemic impact to the revenue cycle, organizational decision-making, clinical protocols, research outcomes and external reporting. The implementation of a Coding Integrity Program within Compliance adds additional structured oversight to monitor accuracy, facilitate improvements and strengthen reporting.
- Compliance Education: Refresh, renew, and rethink all compliance training materials including new employee orientation, annual education, and ad hoc refresher training.
- 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.