COOK COUNTY HEALTH

Cook County Health System Compliance Program

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

January 21, 2022

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I. Executive Summary

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

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

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

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

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

Notable priorities for FY 2022 include:

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

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

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

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

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

- Ongoing monitoring of regulatory changes.

II. Introduction

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

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

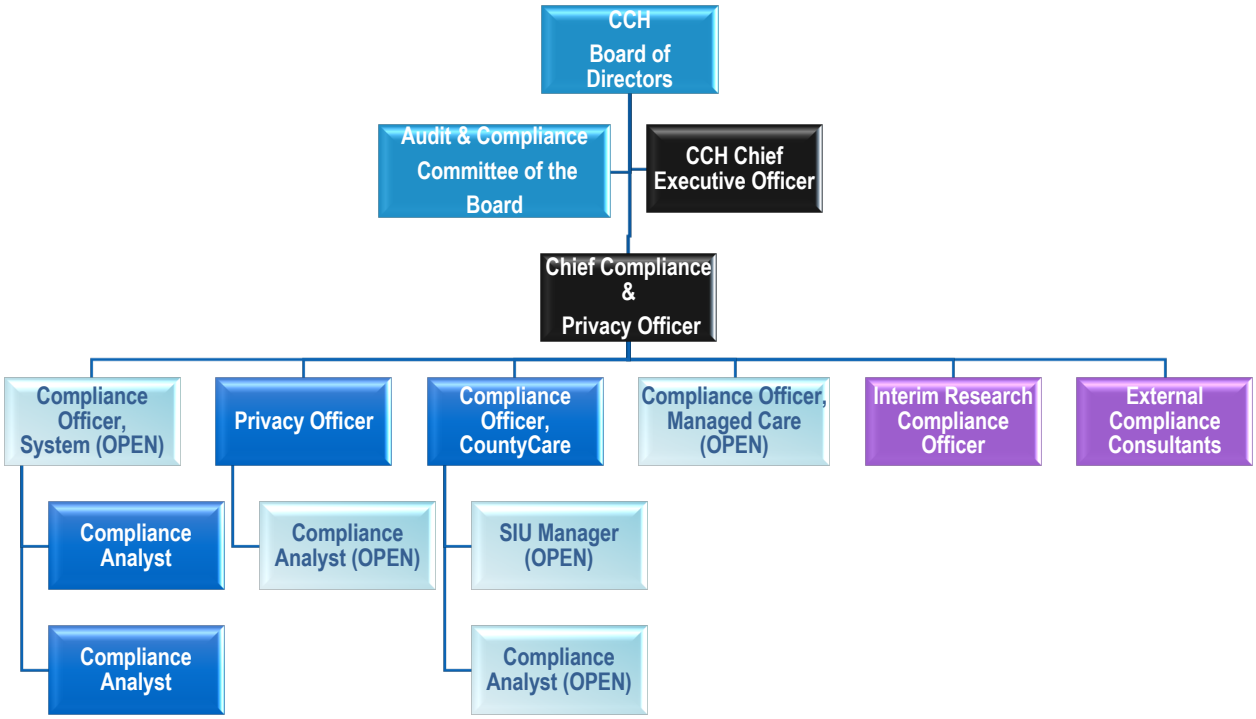
The Annual Report presents the key activities throughout the county fiscal year 2021 (FY 2021) of the System CCH Compliance Program under the executive leadership of Cathy Bodnar, Chief Compliance & Privacy Officer, with support by Dianne Willard, Compliance Officer, Ashley Huntington, Privacy Officer,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

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

III. Building Blocks – Program Infrastructure and Scope

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

Compliance Organizational Chart



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

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

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

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

CCH Compliance Program Scope

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

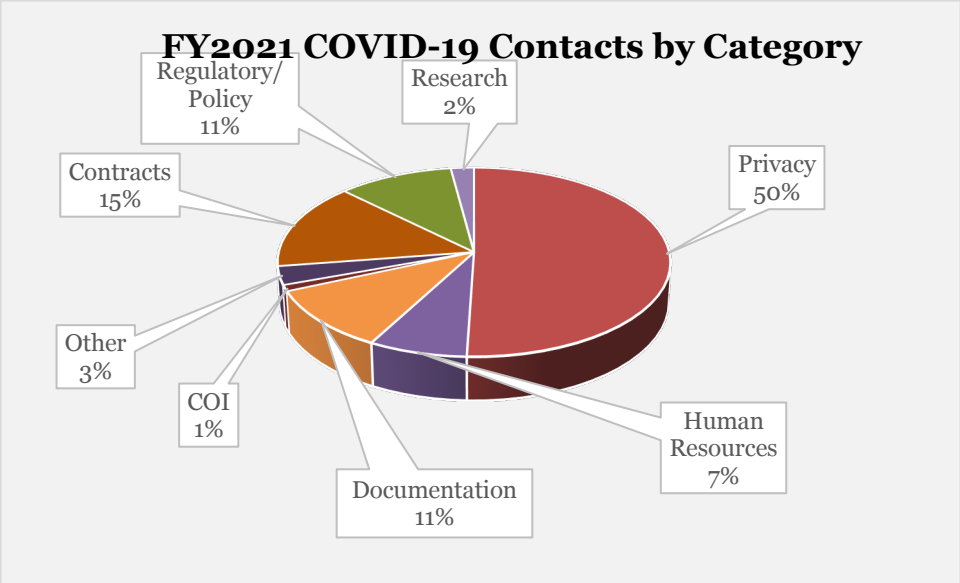
- Interpretation of federal, state, and local laws, rules, and regulations and dissemination of pertinent information to CCH workforce;
- Maintenance and enforcement of the CCH Code of Ethics;
- Assessment and reassessment of CCH Compliance policies and procedures;
- Investigation of allegations of inaccurate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

IV. Ongoing COVID-19 PHE Related Activities

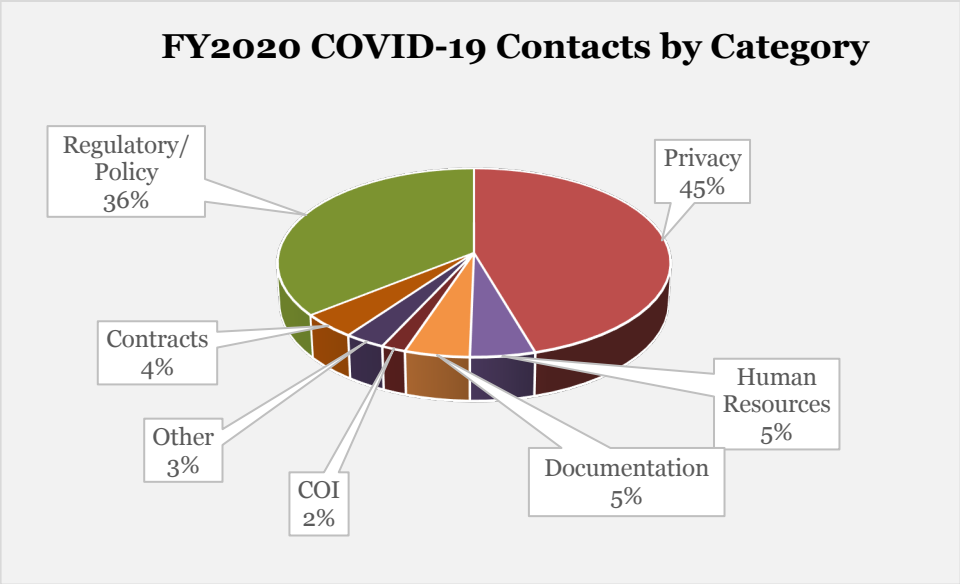
As with FY2020, CCH Compliance's FY2021 work continued to be impacted by COVID-19. In contrast to FY2020, the department maintained an on-site presence of all of its staff for almost the entirety of FY2021. It also carried on its responsibilities for serving as a primary resource for CCH to monitor,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

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

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



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



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

Human Resources	8	Other	5
Documentation	8		

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

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

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

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

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

V. Being Present – Communication – Fostering Transparency

Communication Strategy

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

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

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

Communication Channels

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

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

VI. Compliance Program Structure: Performance of the Elements

Element 1

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

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

Policies and Procedures

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

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

Work Plan Activities

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

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

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

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

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

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

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

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

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

Element 2

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

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

Compliance Office and Committees

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

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

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

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

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

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

Element 3

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

Education and Training

1. New Employee Orientation

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

2. Targeted Education

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

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

3. Annual Compliance Education

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

Element 4

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

Receiving and Responding to Complaints

Infrastructure Activities

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

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

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

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

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

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

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

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

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

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

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

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

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

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

An **A**ssessment occurs,

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

Lastly, the **R**ecommendation,

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

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

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

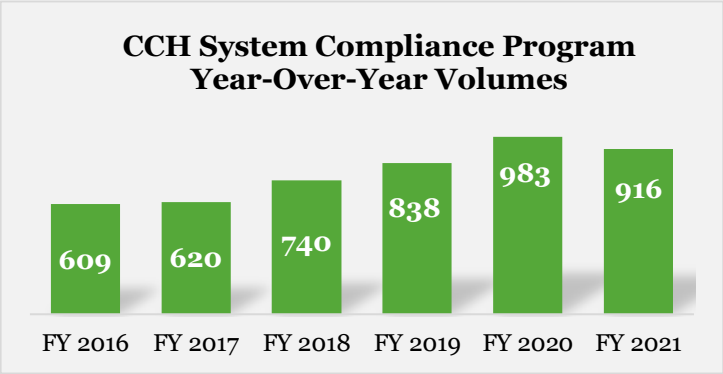
Breaches that affect over 500 individuals must include the following,

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

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

Contact Volumes

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



Contact Breakdown by Category

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

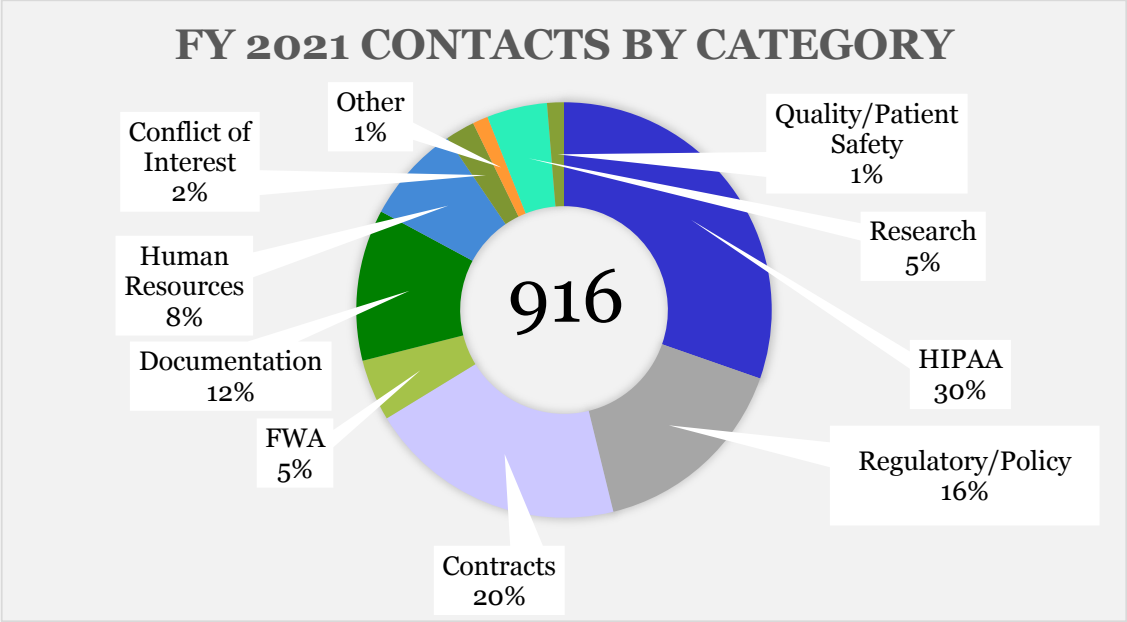
In FY 2021, CCH Compliance continued use of its modified internal tracking system to utilize a COVID-19 check box to identify any COVID-19 related compliance issues that emerged during the pandemic. FY 2021 categories are as follows:

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

FY 2021 Contacts by Category

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

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



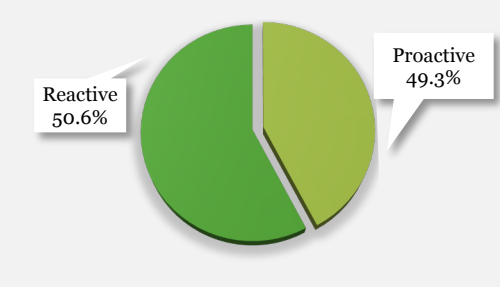
Categories	Count	Categories	Count
Privacy/Security (HIPAA)	278	Contracts	184
Documentation	108	Conflict of Interest	21
Regulatory/ Policy	145	FWA	44
Human Resources	70	Other	11
Research	43	Quality/Patient Safety	12

FY 2021 Contact Status

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

FY 2021 Proactive vs. Reactive

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



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

Element 5

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

Enforcing Standards

Broadened the scope of Standards enforcement through:

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

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

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

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

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

Element 6

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

Auditing and Monitoring

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

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

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

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

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

Risk Assessment

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

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

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

Element 7

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

Sanction Screening Checks

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

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

VII. Looking Ahead to 2022

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

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

Notable priorities for FY 2022 include:

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

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