



COMPLIANCE PROGRAM EVALUATION REPORT

Submitted to:

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EXECUTIVE SUMMARY

The Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) “Compliance Program Guidance for Hospitals” states that it is best practice for a health care organization to periodically have an independent outside expert review its compliance program to assess the effectiveness of the program. Cook County Health (CCH) is following this best practice and hired Strategic Management Services (Strategic Management or “SMS”) to assess the effectiveness of the CCH compliance program and to provide recommendations to improve the compliance program. This report presents the findings and recommendations from that assessment.

Report Overview

Strategic Management concludes the following:

1. The CCH compliance program is led by a dedicated and knowledgeable Chief Compliance & Privacy Officer (Chief Compliance Officer).
2. CCH leadership, including the Chief Executive Officer (CEO), Audit and Compliance Committee Chair, and Chair of the CCH Board of Directors are supportive of the compliance program.
3. The Audit and Compliance Committee of the Board of Directors (Audit and Compliance Committee) and two executive level compliance committees oversee the compliance program. One executive compliance committee oversees the program for the provider health system, and the other oversees the program for the health plan (CountyCare).
4. All committees operate in accordance with their charters which includes receiving regular reports from the Compliance Officer on program status, however consideration should be given to more formal briefing of board members on the ever-changing regulatory and enforcement environment. The meetings are well attended, and members of the committees are engaged and ask questions.
5. The Compliance Office maintains detailed policies and procedures on a wide range of compliance operational matters. CCH also has a Code of Ethics (Code) that is provided to everyone during new hire orientation and as part of annual compliance training. The Code provides an overview of why compliance is important, compliance laws, compliance risks, and the importance of reporting possible or actual compliance violations.
6. The Chief Compliance Officer and her staff were found to be well-regarded by senior management and seen as essential in verifying that CCH operations comply with rules and standards. They are considered accessible and helpful in identifying areas of risk and resolving issues raised by both senior officials and staff at CCH.
7. The Compliance Office recently underwent a staff reduction of 40% that has had a material effect on being able to carry out the assigned duties and responsibilities of the office.
8. CCH provides multiple channels of compliance communication for workforce members to report issues including a Hot Line and an online reporting system. In addition, the Code, policies, and other publicity informs workforce members that they can report issues directly to their supervisor or the

Compliance Office. Interviews with workforce members confirmed they know how to report issues and feel comfortable using the reporting lines.

9. The Compliance Office tracks all reported issues and audits in a web-based tracking tool. The Compliance Tracker was developed in Salesforce leveraging an existing system licensure. The Compliance Tracker provides high level dashboards of contacts brought to the attention of Corporate Compliance and details for each case, whether open or closed. The Compliance Office provided screenshots and a demonstration of how the Compliance Tracker works. A Cook County email address is required to access the data in the Compliance Tracker, so the Compliance Office also provided an excel spreadsheet that included a summary of reported issues.
10. Workforce members in interviews stated that the Compliance Office is quick to respond to reported issues and compliance questions.
11. The Compliance Office conducts audits on compliance risks, mostly in response to identified issues. However, the Compliance Office and other workforce members reported that the Compliance Office is not currently doing proactive audits because of staffing limitations.
12. The CCH Internal Audit department annually identifies risks that are used to create their work plan for the year, which is created through interviews with department leads, including the Compliance Office. However, the Compliance Office did not complete an annual risk assessment specific to compliance risks at CCH for FY 2021. Although the Compliance Office completed a risk assessment for FY 2020, it was unable to executive a full and complete risk assessment due to the public health emergency and reductions in the staff. Since compliance lacks the staff to complete and execute a compliance risk assessment, compliance and internal audit should work together and simultaneously to interview organizational leaders, identify respective risks, and create an enterprise wide risk assessment that addresses compliance risks either permanently or until the Compliance Office is fully staffed.
13. Audits that resulted from risk identified in the 2019 compliance risk assessment were completed and reported to the Audit and Compliance Committee.
14. The Compliance Office created a Strengths, Weaknesses, Opportunities, and Threats (SWOT) matrix to identify risks and goals for compliance for the CEO in 2021.
15. All new employees are required to take compliance training during orientation. All current employees are required to take compliance training on an annual basis. It is also a standard contract term with all vendors that the vendor will ensure employees receive compliance training upon hire and annually thereafter.
16. CCH conducts exclusion screening checks on all new employees and vendors and the Compliance Program conducts monthly screenings of existing employees and vendors.

The following opportunities should be considered as the more significant suggestions to enhance the program. Additional details are in the body of this report.

Oversight:

1. The Compliance Office currently consists of the Chief Compliance and Privacy Officer, three leadership positions in the form of Compliance Officer-System, Compliance Officer-CountyCare (Vacant), Privacy Officer, and two compliance analysts and one vacant compliance analyst position to support compliance leadership. The reduction in Compliance Office resources has prevented it from fulfilling its full scope of oversight responsibilities. It is suggested that at least 3 full-time employees (FTEs) be added to the current Compliance Office organizational structure of 7 FTEs.
2. Charters of oversight committees can be enhanced, principally by including language that requires an annual self-review by the Committee(s) of performance against their charters. In addition, the Regulatory Compliance Committee Charter should be expanded to provide more detail regarding membership, duties, and responsibilities.
3. The Chief Compliance Officer has a dual reporting relationship to the CCH Board of Directors through the Audit and Compliance Committee of the Board and the CEO.
4. The Chief Compliance Officer should periodically review the membership of the CCH Corporate Compliance Steering Committee and the CountyCare Regulatory Compliance Committee and make changes as appropriate.
5. The Board Audit and Compliance Committee should ensure at least one member is “compliance literate” and possesses sufficient compliance experience and expertise to assist the Committee in raising questions about the compliance program and in evaluating performance.
6. The Chair of the Audit and Compliance Committee should provide input in the performance evaluation and compensation decisions regarding the Chief Compliance Officer, as well as reviewing and approving Compliance Office work plans and available resources to carry them out.
7. The members of the Board of Directors and the Audit and Compliance Committee should receive additional periodic education on compliance, their oversight duties, and current regulatory risks areas. Compliance should be given an opportunity through additional time at all the Audit and Compliance Committee meetings to provide briefings and education.
8. The Audit and Compliance Committee should formally review and approve compliance budgets.

Compliance Guidance:

9. The Code could be enhanced by including an introduction letter from the CEO to further emphasize the importance of compliance throughout the organization.
10. Additional compliance policies should be created as follows:
 - Standalone Non-retaliation Policy
 - Standalone Anonymous Reporting Policy
 - Standalone Confidentiality Policy
 - Policy for Coordination with Human Resources (HR)
 - Policy for Coordination with Legal Counsel

- Performance Evaluation of Compliance Policy
- Responding to Subpoenas and Requests for Information
- Search Warrant Policy

Training and Education:

11. CCH should update the questions on their compliance training to be more scenario-based. This will allow for greater retention of the material and prevent employees from quickly skipping through the training.
12. The Compliance Office should also use other opportunities, such as newsletters or targeted education to increase compliance knowledge and be more visible throughout CCH.

Auditing and Monitoring:

13. The Compliance Office should re-initiate a formalized risk assessment that will inform audits conducted throughout the year.
14. Compliance should work with operational leadership to educate operational departments on what monitoring processes should be in place and what areas of risk should be monitored.

Lines of Communication:

15. The Compliance Office, in partnership with Quality and Patient Safety should better-educate staff on what to report to the compliance Hot Line and what should be reported in the eMERs system.

Compliance Enforcement and Sanction Screening:

16. The Compliance Office should update its Sanction Screening policy to include language that indicates compliance conducts monthly and annual screening of vendors.

Investigations and Corrective Action Plans:

17. Compliance should continue to work in partnership with operational departments to ensure they implement corrective action plans (CAPs) and correct compliance deficiencies found through audits and investigations.

BACKGROUND AND METHODOLOGY

Cook County Health (CCH) is a comprehensive, fully integrated public healthcare delivery system that serves the Cook County, Illinois community. The annual budget is approximately \$3 billion. CCH includes two hospitals, John H. Stroger, Jr., an academic medical center, and Provident Hospital of Cook County, a community hospital, Cermak Health Services of Cook County in Cook County Jail and the Temporary Juvenile Detention Center, a network of Ambulatory and Primary Care centers, and Cook County Public Health Department. CCH is responsible for the oversight, management, and administration of the Cook County Health Plan, CountyCare. CCH has around 8,000 workforce members.

Strategic Management started its independent Compliance Program Review of Cook County Health in February 2021. Steven Forman, CPA and SMS Senior Vice President, and Alexis Rose, JD and Consultant conducted the review. Strategic Management provided the Chief Compliance Officer with a document request on February 12, 2021. Strategic Management had a kick-off call with the Chief Compliance Officer and Compliance Office leadership on March 01, 2021, prior to interviewing other CCH workforce and members of leadership. During the review, Strategic Management was granted unrestricted access and received full cooperation and support from CCH. Strategic Management met with the Chief Compliance Officer several times throughout the process to provide updates and receive additional information.

SMS's methodology in performing the Compliance Program Review included:

- Examination and analysis of existing Compliance Program documentation.
- WebEx and Zoom video interviews with twenty-three executives and staff and two focus groups.
- Review of Compliance training modules.
- Validation testing of Ineligible Persons screening, annual and new hire training, and Code attestation.
- Observation of an Audit and Compliance Committee meeting and a Regulatory Compliance Committee meeting.

Document Request and Reviews:

SMS formally requested and electronically received and reviewed numerous CCH Compliance Program policies and procedures and related documents. Throughout the review, CCH responded to requests for additional information and documents. For the review, SMS received documentation including:

- Organizational Chart;
- Compliance Program Annual Report;
- Charter, meeting minutes, and meeting presentations for the Audit and Compliance Committee to the Board;
- Charter, meeting minutes, and meeting presentations for the executive level Compliance Committees;
- Chief Compliance & Privacy Officer and Compliance Officers job descriptions;
- Compliance training materials;
- Compliance Program budget;
- Code of Ethics;
- Compliance Program policies and procedures;
- Risk Assessment;
- Examples of compliance audits;

- Compliance resolution tracking report;
- Hot Line materials; and
- Sanction Screening materials.

Strategic Management (virtually) interviewed the following CCH Board Members and employees:

- Israel Rocha, CCH Chief Executive Officer
- Tom Schroeder, System Director of Internal Audit
- Andrea Gibson, Interim Chief Business Officer
- Carrie Pramuk-Volk, Interim Chief Human Resources
- Mike Koetting, Chair of the Audit and Compliance Committee
- Claudia Fegan, MD, Interim Chief Medical Officer
- Jeff McCutchen, General Counsel
- Aaron Galeener, Interim CEO Health Plan Services
- Manny Estrada, COO of Cermak Health Services
- Linda Kampe, Assistant Administrator of Cermak Health Services
- Suja Mathew, MD, Chair of Department of Medicine
- Beena Peters, Chief Nursing Officer
- Hill Hammock, Chair of the Board
- Robert Sumter, Chief Information Officer/COO
- Iliana Mora, Chief Operating Officer -Ambulatory Services
- Yvonne Collins, MD, Chief Medical Officer-Health Plan Services
- Esther Macchione, Chief Operating Officer-Health Plan Service
- Charles Jones, Chief Procurement Officer
- Annie Peterson, Director of Revenue Cycle
- Leathecia Arnold, Director of Health Information Management
- Jerry Pagell, Security and Network Information Officer/Interim Security Officer
- Audrey French, MD, Director of HIV Services, and Institutional Review Board

In addition to the interviews, SMS conducted two focus group meetings, one with first and second-line managers and the second with operating level employees.

SMS conducted activities to gain insight into some of the functions of the Compliance Program, including:

- Observation of a Board of Directors meeting;
- Observation of a Steering Committee meeting; and
- Validation testing of the Hot Line, Ineligible Persons screening, training completion, and Code of Ethics training.

COMPLIANCE PROGRAM GUIDANCE

Federal authorities, including the U.S. Sentencing Commission and the Department of Health and Human Services Office of Inspector General (OIG), and the Department of Justice (DOJ) have issued considerable guidance on how to implement an effective compliance program and specific areas of risk. The guidance includes the following:

- U.S. Sentencing Commission, Guidelines Manual 2018, Chapter 8, Part B.
- HHS OIG. Compliance Program Guidance for Hospital (23 Feb. 1998).
- HHS OIG. Supplemental Compliance Program Guidance for Hospitals. (31 Jan. 2005).

- U.S. Department of Justice, Criminal Division, Fraud Section, Evaluation of Corporate Compliance Programs (Updated June 2020).
- U.S. Department of Justice, Criminal Division. Fraud Section, Evaluation of Corporate Compliance Programs. (8 Feb. 2017).
- Additional Guidance including;
 - March 27, 2017—"Measuring Compliance Program Effectiveness: A Resource Guide"
 - April 20, 2015—"Practical Guidance for Health Care Governing Board on Compliance Oversight"
 - February 27, 2012—"Handout: A Toolkit for Health Care Boards"
 - August 29, 2011—"The Health Care Director's Compliance Duties: A Continued Focus of Attention and Enforcement"
 - March 23, 2009—"Driving for Quality in Acute Care: A Board of Directors Dashboard-Government-Industry Roundtable"
 - January 31, 2008—"Driving for Quality in Long-Term Care: A Board of Directors Dashboard-Government-Industry Roundtable"
 - September 13, 2007—"Corporate Responsibility and Health Care Quality- A Resource for Health Care Boards of Directors"
 - December 2, 2004—"Continuing the Partnership: A Summary of the Government-Industry Roundtable on the Role of Governance in Compliance Programs"
 - July 1, 2004—"An Integrated Approach to Corporate Compliance: A Resource for Health Care Boards of Directors"
 - April 2, 2003—"Corporate Responsibility and Corporate and Corporate Compliance: A Resource for Health Care Boards of Directors"
 - August 2013—"Expanding Physician Education in Health Care Fraud and Program Integrity"
 - September 25, 2000—"Building a Partnership for Effective Compliance-A Report of the HCCA"-OIG Physician's
 - April 14, 1999—"Building a Partnership for Effective Compliance- A Report on the Government-Industry Roundtable"
- Corporate Integrity Agreements published by the OIG.
- OIG Special Fraud Alerts, Bulletins and Other Guidance dealing with specific types of transactions or arrangements.

The Compliance Program guidance provides several distinct themes:

1. Each organization is different, and the compliance program must be tailored to the organization and culture, however the seven standard elements of the U.S. Sentencing Commission and OIG compliance guidance documents must be present and effective. It is the responsibility of the organization to evidence that their compliance program is operating in an effective manner.
2. A top-down program beginning at the board and executive level is critical to the success of the compliance program. It places a major burden on leadership to oversee the compliance program and ensure it is operating as it should.
3. All providers have the obligation to address and report non-compliance of applicable laws, regulations, and payment rules in a timely and thorough manner. Oversight committees must take the lead in ensuring this is being done.

4. The compliance program should undergo an independent review periodically to verify that it is operating in an effective manner.
5. Quality of care and compliance are viewed by the OIG as being closely related. Laws, regulations, and rules are created to protect patients and those who care for them. A successful compliance program will benefit the organization in many ways, the first being better care for patients.

The OIG issued in 2005 the *Supplemental Compliance Program Guidance for Hospitals* (“Supplemental Guidance”), wherein they state: *“Building and sustaining a successful compliance program rarely follows the same formula from organization to organization. However, such programs generally include: the commitment of the hospital’s governance and management at the highest levels; structures and processes that create effective internal controls; and regular self-assessment and enhancement of the existing compliance program.”*

The OIG stresses, *“It is incumbent upon corporate officers and managers to provide ethical leadership to the organization and to assure that adequate systems are in place to facilitate ethical and legal conduct. Indeed, many hospitals and hospital organizations have adopted mission statements articulating their commitment to high ethical standards. A formal compliance program, as an additional element in the process, offers a hospital a further concrete method that may improve quality of care and reduce waste. Compliance programs also provide a central coordinating mechanism for furnishing and disseminating information and guidance on applicable federal and state statutes, regulations and other requirements.”*

The Department of Justice (DOJ) and the OIG have emphasized that to have an effective compliance program, an organization must have an effective method for “risk assessment.” The DOJ Guidelines outline how critical risk assessments are with the following language:

The starting point for a prosecutor’s evaluation of whether a company has a well-designed compliance program is to understand the company’s business from a commercial perspective, how the company has identified, assessed, and defined its risk profile, and the degree to which the program devotes appropriate scrutiny and resources to the spectrum of risks... What compliance expertise has been available on the board of directors? Have the board of directors...held executive or private sessions with the compliance and control functions? What types of information have the board of directors and senior management examined in their exercise of oversight in the area in which the misconduct occurred? What types of information have the board of directors and senior management examined in their exercise of oversight in the area in which the misconduct occurred?

The document *“Practical Guidance for Health Care Governing Boards on Compliance Oversight”* states the following: *“Previous guidance has consistently emphasized the need for Boards to be fully engaged in their oversight responsibility. A critical element of effective oversight is the process of asking the right questions of management to determine the adequacy and effectiveness of the organization’s compliance program, as well as the performance of those who develop and execute that program, and to make compliance a responsibility for all levels of management... Boards should develop a formal plan to stay abreast of the ever-changing regulatory landscape and operating environment. The plan may involve periodic updates from informed staff or review of regulatory resources made available to them by staff.”*

In terms of information flow, the Guidance states: *“A Board must act in good faith in the exercise of its oversight responsibility for its organization, including making inquiries to ensure: (1) a corporate information and reporting system exists and (2) the reporting system is adequate to assure the Board that appropriate information relating to compliance with applicable laws will come to its attention timely and as a matter of course.”*

In terms of design, the Guidance states: *“Although compliance program design is not a “one size fits all” issue, Boards are expected to put forth a meaningful effort to review the adequacy of existing compliance systems and functions. Ensuring that management is aware of the Guidelines, compliance program guidance, and relevant CIAs is a good first step.”*

In terms of risk, the Guidance states: *“Boards should also evaluate and discuss how management works together to address risk, including the role of each in:*

- 1. identifying compliance risks,*
- 2. investigating compliance risks and avoiding duplication of effort,*
- 3. identifying and implementing appropriate corrective actions and decision-making, and*
- 4. communicating between the various functions throughout the process.”*

The 2020 Department of Justice “Compliance Program Effectiveness Evaluation Guidelines” add the following considerations:

- 1. Is the compliance program adequately designed for maximum effectiveness in preventing and detecting wrongdoing by employees and is corporate management enforcing the program or tacitly encouraging or pressuring employees to engage in misconduct?*
- 2. Was the program designed to understand the company’s business from a commercial perspective?*
- 3. Why the company has chosen to set up the compliance program the way that it has, and why and how the company’s compliance program has evolved over time?*
- 4. Is the program appropriately designed to detect the types of misconduct most likely to occur in a corporation’s line of business and complex regulatory environment?*

REVIEW RESULTS

The findings incorporated in this report, along with the suggestions and recommendations, are the direct result of the Strategic Management review process. Findings and recommendations are presented by sections that parallel the seven elements of a compliance program as described by the U.S. Sentencing Commission and the OIG.

1. COMPLIANCE PROGRAM OVERSIGHT & MANAGEMENT

Guidance:

In its original (1998) “Compliance Program Guidance for Hospitals,” the OIG stresses that *“at a minimum, comprehensive compliance programs should include...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 report directly to the CEO and the governing body.”*

The OIG indicates the need for a board level committee, as well as an executive-level committee consisting of cognizant, senior managers in the organization.

With regard to a senior management level compliance committee, the OIG guidance states that *“a compliance committee be established to advise the compliance officer and assist in the implementation of the compliance program....The compliance committee benefits from having the perspectives of individuals with varying responsibilities in the organization, such as operations, finance, audit, human resources, utilization review, social work, discharge planning, medicine, coding and legal, as well as employees and managers of key operating units.”*

In April 2003, the OIG and the American Health Lawyers Association (AHLA) jointly published *“Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors.”* The document suggests a number of questions board members should be asking including the following under *“Structural Questions.”*

“1. How is the compliance program structured and who are the key employees responsible for its implementation and operation? How is the Board structured to oversee compliance issues?”

The document states further: *“The success of a compliance program relies upon assigning high-level personnel to oversee its implementation and operations. The Board may wish as well to establish a committee or other subset of the Board to monitor compliance program operations and regularly report to the Board.”*

The OIG’s *“Practical Guidance for Health Care Governing Boards on Compliance Oversight”* states; *“Boards should be aware of, and evaluate, the adequacy, independence, and performance of different functions within an organization on a periodic basis. OIG believes an organization’s Compliance Officer should neither be counsel for the provider, nor be subordinate in function or position to counsel or the legal department, in any manner. While independent, an organization’s counsel and compliance officer should collaborate to further the interests of the organization.”*

Boards should develop a formal plan to stay abreast of the ever-changing regulatory landscape and operating environment. The plan may involve periodic updates from informed staff or review of regulatory resources made available to them by staff.

The Committee should also make informed strategic decisions regarding the organizations’ compliance programs, including matters that relate to funding and resource allocation. In the DOJ Guidelines from June 2020, the DOJ also provides many questions concerning the Compliance Office function that largely revolve around the adequacy of empowerment, independence and autonomy for the Compliance Officer, the Compliance Officer reporting relationship to executive leadership and the Board, and the adequacy of staff and resource levels for the compliance program... A Board can raise its level of substantive expertise with respect to regulatory and compliance matters by adding to the Board, or periodically consulting with, an experienced regulatory, compliance, or legal professional. The presence of a professional with health care compliance expertise on the Board sends a strong message about the organization’s commitment to compliance, provides a valuable resource to other Board members, and helps the Board better fulfill its oversight obligations. Board members are generally entitled to rely on the advice of experts in fulfilling their duties. The OIG sometimes requires entities under a CIA to retain an expert in compliance or governance issues to assist the Board in fulfilling its responsibilities under the CIA. Experts can assist

Boards and management in a variety of ways, including the identification of risk areas, provision of insight into best practices in governance, or consultation on other substantive or investigative matters. As part of its oversight responsibilities, the Board may want to consider conducting regular “executive sessions” (i.e., excluding senior management) with leadership from the compliance, legal, internal audit, and quality functions to encourage more open communication. Scheduling regular executive sessions creates a continuous expectation of open dialogue, rather than calling such a session only when a problem arises and is helpful to avoid suspicion among management about why a special executive session is being called.

The OIG and AHLA issued a joint publication entitled “Measuring Compliance Program Effectiveness.” It stressed that commitment from the top (Board level) was critical and that they should review compliance program resources (budget, staff) and approve the compliance budget. The determination of the budget should be based on an assessment of risk and program improvement/effectiveness. Sufficient compliance program resources (budget, staffing) must be available to ensure significant risks are managed appropriately

FINDINGS

Summary. CCH has an Audit and Compliance Committee to the Board of Directors (Audit and Compliance Committee) that meets on a quarterly basis and receives reports from the Chief Compliance Officer. CCH also has two executive level compliance committees, one that oversees the compliance program for the health system and one that oversees the compliance of the CountyCare health plan. Both the Audit and Compliance Committee and executive level committees have active and well attended meetings as evidenced by minutes and presentations maintained of meetings. Charters of the Audit and Compliance Committee and the two Executive Compliance Committees can be enhanced.

The Chief Compliance Officer is knowledgeable and well respected by senior staff. However, a reduction in resources has limited the ability of the Compliance Office to carry out its responsibilities, particularly with regard to auditing and monitoring functions and outreach.

The following are more specific comments and findings about compliance program oversight:

1. CCH has a twelve-member Board of Directors that was established through a Cook County ordinance. The ordinance states, *“The Directors may establish such additional committees and appoint such additional officers for the System Boards as they may deem appropriate, however, at a minimum, the Directors shall establish standing . . . audit and compliance committee.”* The Board meets on a quarterly basis to hold public Board meetings.
2. The Board has established an Audit and Compliance Committee. In 2010, CCH created a Charter for the Audit and Compliance Committee, which was last updated in 2015. The Charter outlines the responsibilities of the Committee, including to *“[p]rovide oversight to the implementation of the corporate compliance program, and ensure adherence to the Standards of Conduct and Governmental Rules and Regulations and recommended any revisions thereto, as appropriate.”*
3. The Charter also states that the Audit and Compliance Committee will meet with the Chief Compliance Officer periodically to keep informed of independent evaluations and legal and regulatory practices.

4. CCH maintains a “Rules of Organization and Procedure of the Board of Directors of the Cook County Health and Hospital System,” that outlines the requirements of the Board. The document outlines the primary duties of the Audit and Compliance Committee. The document states, *“the Committee will assist the System Board in fulfilling its oversight responsibilities of the CCH corporate compliance effort.”*
5. The Audit and Compliance Committee is also charged with the review and approval of the annual internal audit and corporate compliance program plans and monitoring the ongoing progress of said plans.
6. There is no provision in the Audit and Compliance Committee Charter for its regular review. Generally, such charters are reviewed annually or in some cases bi-annually.
7. In addition, there is no provision in the charter for the Audit and Compliance Committee to review the Committee’s performance at least periodically against its prescribed duties and responsibilities in the charter. This involves reviewing the compliance program resources (budget, staff) and approval of the compliance budget based on an assessment of risk and program improvement/effectiveness. Sufficient compliance program resources (budget, staffing) must be available to ensure significant risks are managed appropriately
8. The Committee, on behalf of the Board, should develop a formal plan to stay abreast of the ever-changing regulatory landscape and operating environment. This should include being provided periodic updates from informed staff or review of regulatory resources made available to them by staff
9. In accordance with its charter, the Audit and Compliance Committee meets at least four times a year prior to Board meetings.
10. CCH maintains minutes of all Audit and Compliance Committee meetings. The minutes and meeting packages evidence that the Chief Compliance Officer provides comprehensive reports to the Committee at each meeting.
11. The Chief Compliance Officer creates presentations for Audit and Compliance Committee meetings that include updates on the types of compliance contacts received from the Hot Line and other sources. The presentations also provide updates on the progress of the Compliance Program’s annual work plan items.
12. Although the Audit and Compliance Committee are informed of compliance activities within CCH, the members may also benefit from additional periodic education on their oversight duties as members of governance and current regulatory risks.
13. The Chief Compliance Officer and Chair of the Audit and Compliance Committee meet before Committee meetings to have an in-depth discussion of the topics that will be presented at the upcoming meeting. The other Committee members receive the materials a week prior to the meeting for review.
14. It was reported that all Board members attend the Audit and Compliance Committee meetings.

15. CCH also has two executive level compliance committees, the “Corporate Compliance Steering Committee” which is responsible for oversight of the provider system and the “Regulatory Compliance Committee” is responsible for oversight of the CountyCare Health Plan.
16. The Steering Committee adopted a charter in 2013. The Charter states that the Chief Compliance Officer will chair the Steering Committee, and the members of the Steering Committee are the Executive Leadership team members. The Steering Committee meets at least four times a year. The Charter states that the primary responsibilities of the Committee include monitoring the effectiveness of the compliance program, reviewing the annual corporate compliance work plan, assisting the Chief Compliance Officer with analyzing the regulatory environment, recommending actions to strengthen the compliance program, and reviewing issues, concerns, and trends identified that pose a significant risk.
17. The Regulatory Compliance Committee Charter is brief. It only states that the Committee is responsible for disseminating information related to the regulatory environment, fraud, waste, and abuse, risk areas, HIPAA, and contractual and regulatory requirements. The Charter states the Committee will also be responsible for monitoring plans of correction. There is no information on who chairs the Committee, it’s composition, meeting cadence, review requirements, or self-assessment. In addition, the Charter for the Regulatory Compliance Committee does not have an adoption date or date of last review.
18. The Compliance Steering Committee Charter was last reviewed and updated in 2015. However, the Charter states that it will be reviewed every two years.
19. Interviews with the Chair of the Audit and Compliance Committee and Chair of the Board of Directors showed there is a clear understanding of compliance and compliance risks.
20. Strategic Management observed both a meeting of the Audit and Compliance Committee to the Board and a meeting of the Regulatory Compliance Committee. In both meetings, the Chief Compliance Officer provided a formal presentation to the Committee members at the beginning of the meeting. The meetings were then open to questions and conversation, and members seemed to be engaged with questions.
21. The Compliance Office also creates in-depth Annual Reports for both the Steering Committee and the Regulatory Compliance Committee. The Annual Reports outline actions that the Compliance Office is taking in each area of an effective compliance program. It also reports on the planned compliance activities for the upcoming year.
22. The CCH Board meetings are public meeting where attendance is open to anyone. Certain subjects are permitted to be discussed in closed session, but compliance is not one of those topics. There is no opportunity for close sessions on compliance matters unless they are also legal, employment or internal audit matters.
23. The Compliance Office is composed of the Chief Compliance and Privacy Officer, a Privacy Officer, a Compliance Officer for the system, and two compliance analysts. Vacancies exists for a Compliance Officer dedicated to CountyCare Medicaid Health Plan and another Compliance Analyst. External

consultants provide significant support to the Compliance Program, including full-time support of the Compliance function within CountyCare, part-time support to develop a Research Compliance Program, in addition to intermittent support on issues and projects.

24. Given the responsibility to oversee what amounts to two compliance programs—one for a healthcare provider and the other for a health plan, the Compliance Office is significantly under-resourced and over-taxed in meeting the obligations of the function. Cook County Health is a complex, \$3 billion a year operation that must navigate in a challenging and dynamic regulatory environment. According to the latest Health Care Compliance Association Survey, 75% of the organizations that produce from \$1 to 3 billion in revenue have at least 6-10 people in the Compliance Department. Based on the same survey a little more than half of the organizations that employ from 5,000 to 7,500 people have at least 6-10 people in the Compliance Department. It should also be pointed out there are only 4 people in the Internal Audit (IA) Department and while IA does work with compliance on occasion, such as when there is a coding issues found during a revenue cycle audit, its ability to support the Compliance Program, especially given the broad scope of its responsibilities will be very limited. As a result, what has transpired is the Compliance Office is predominantly reactive—it responds to issues raised through the various reporting channels rather than help to lead the organization in addressing risk through the more proactive activities of auditing and monitoring. The staff limitations have also inhibited the Compliance Office’s ability to carry out another critical responsibility—relationship-building with the management team throughout the organization. Both are very important in the long-term success and effectiveness of a compliance program.
25. The reduction in resources has also impacted education of the compliance staff. It is important for members of the Compliance Office to be well educated on compliance matters and to keep up with compliance and regulatory trends in order to properly address risks and proper implementation of compliance controls.
26. The Chief Compliance Officer is experienced and well respected by leadership. Many interviews confirmed that the Compliance Office is responsive to questions and reported issues.
27. Some reported having a concern that when the Compliance Office is involved in something or wants to talk to them, they are going to get “in trouble” because they have done something to that caused a compliance investigation. In part this may be a result of the fact that Compliance Staff is spread so thinly and simply interacts with departments only when there is an investigation or audit. However, it was also reported that this feeling is changing, and less people are of the mindset that they will get “in trouble.”
28. Some workforce members reported that it is not always clear the scope of the Compliance Office’s functions and responsibilities. The Compliance Office also reported that they often take on tasks that are outside the scope of a compliance department because operational departments do not have the expertise or willingness to complete them. One example cited was developing plans of correction from reviews or investigations.
29. CCH maintains formal job descriptions for the Chief Compliance Officer and Compliance Officers for both CountyCare and the health system. The Chief Compliance & Privacy Officer job description includes all duties expected of a compliance officer. The Chief Compliance Officer has a dual reporting line to the CEO and the Board of Directors. The Audit and Compliance Committee Charter under

“Procedures” states, “The Committee shall: Have the authority to hire, terminate, and determine the compensation for the Chief Compliance Officer and the Director of Internal Audit.” It was reported that the Audit and Compliance Committee does not participate or provide input into the annual performance evaluation of the Compliance Officer.

30. The CEO confirmed that he meets with the Chief Compliance Officer during regularly scheduled meetings and on an ad hoc basis as needed.

RECOMMENDATIONS/SUGGESTIONS

Key suggestions that management should consider are summarized as follows:

1. The Audit and Compliance Committee Charter should be:
 - Reviewed and updated more frequently.
 - Include a provision for an annual review of its function.
 - Call for the Committee to perform annual a self-assessment of its performance.
 - Consider requiring at least one member of the Committee to be compliance literate, meaning have expertise, knowledge and experience with compliance programs.
2. The Audit and Compliance Committee, on behalf of the Board, should develop a formal plan to stay abreast of the ever-changing regulatory landscape and operating environment. It is advisable to have the Compliance Officer present updates at each meeting with the Committee regarding changes in the legal and regulatory environment, including changes in laws, new guidelines such as those provided by the DOJ in 2020, OIG, CMS, and OIG workplan and published priorities, etc.
3. In meeting their obligations, the Audit and Compliance Committee is also charged with the review and approval of the annual internal audit and corporate compliance program plans and monitoring the ongoing progress of said plans. In order to meet this obligation, it is critical that they ensure the Compliance Office has adequate budget and qualified staff resources available to meet their obligations.
4. The Audit and Compliance Committee, particularly the Chair, should be involved in the performance evaluation of the Chief Compliance Officer, as called for in the Charter. This includes active involvement in the reviewing of the adequacy of compliance program resources (budget, staff).
5. It is recommended that the Committee review and approve the compliance budget, based on an assessment of risks and program improvement/effectiveness; and ensure sufficient compliance program resources (budget, staffing) are allocated to address all the duties and obligations of the compliance program operation.
6. CCH should ensure that it reviews the Compliance Steering Committee Charter every two years in accordance with the Charter. Consideration should be given to having an annual review.
7. The Regulatory Compliance Committee Charter was updated last year. However, it should undergo review that includes making changes that include:
 - Requiring an annual review by the Regulatory Compliance Committee.
 - Adding a provision whereby the Committee performs an annual assessment of its performance.

- Adding operating details—e.g., who chairs the meetings; the composition of the committee; required number of meetings; need to take minutes; need for meeting agendas, etc.
 - Providing expanded, more detailed, information on the duties and responsibilities of the Committee.
 - Setting a date of review/revision to the Regulatory Compliance Committee Charter.
8. Periodically, the Chief Compliance Officer in conjunction with the CEO should review who should be on the Compliance Steering Committee and the Regulatory Compliance Committee.
 9. The members of the Board of Directors and the Audit and Compliance Committee should receive additional periodic education on compliance, their oversight obligations, and current regulatory risks areas. Compliance should be given an opportunity through additional time at the Audit and Compliance Committee meetings to provide this education.
 10. The Compliance Office is under-staffed, especially given the size and complexity of CCH, and the fact that the Office is tasked with administering two compliance programs. Strategic Management recommends that staffing be increased by a minimum of 3 FTE's. The additional FTEs should include at least one analyst and one manager who has education and a good understanding around auditing activities for the CountyCare Compliance Team, as the focus of the additional FTE's would be as follows:
 - Enhancing auditing and monitoring and follow-up of plans of correction both on the provider and the plan side. This includes working with operational management to establish risk-based monitoring, thereby increasing the leverage of the Compliance Office in leading CCH to adequately address its compliance risk areas.
 - Outreach with the operating departments with the goal of building additional relationships within CCH operations and educating managers and staff on the role and functions of the Compliance Office.
 11. In addition to increasing the Compliance Office staff, Compliance should be provided with the proper resources to educate compliance staff upon hire and periodically after using compliance experts and professional trade organizations. Compliance should also have the resources to continue education of its staff on targeted compliance issues and professional standards to ensure that the Compliance Office is staffed with individuals qualified to identify current risks, remediate risks, and implement appropriate compliance standards and tools.

2. WRITTEN COMPLIANCE GUIDANCE

Guidance:

The 1998 OIG guidance for hospitals states that *“At a minimum, comprehensive compliance programs should include...Development and distribution of written code or standards of conduct, 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, code gaming, and financial relationships with physicians and other health care professionals.”*

With regard to the Code of Conduct, the OIG and AHHA's "Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors" states, "Regardless of its title, a Code of Conduct is fundamental to a successful compliance program because it articulates the organization's commitment to ethical behavior. The Code should function in the same way as a constitution, i.e., as a document that details the fundamental principles, values, and framework for action within the organization. The Code of Conduct helps define the organization's culture; all relevant operating policies are derivative of its principles. As such, codes are of real benefit only if meaningfully communicated and accepted throughout the organization."

With regard to policies, the document states, "If the Code of Conduct reflects the organization's ethical philosophy, then its policies and procedures represent the organization's response to the day-to-day risks that it confronts while operating in the current health care system. These policies and procedures help reduce the prospect of erroneous claims, as well as fraudulent activity by identifying and responding to risk areas. Because compliance risk areas evolve with the changing reimbursement rules and enforcement climate, the organization's policies and procedures also need periodic review and, where appropriate, revision."

The DOJ 2020 Guidelines place emphasis on compliance documents, including the Code of Conduct and compliance policies and procedures ("P/Ps"). Examples of questions they ask include the following:

1. Is there a code of conduct that sets forth commitment to full compliance with applicable laws?
2. Have P/Ps been implemented that incorporate the culture of compliance into its day-to-day operations?
3. What is the process for designing, implementing, and updating P/Ps, and has it changed over time?
4. Who has been involved in the design of P/Ps?
5. What efforts are made to monitor and implement P/Ps that reflect and deal with the spectrum of compliance risks, including changes to the legal and regulatory landscape?
6. How have P/Ps been communicated to employees and relevant third parties?
7. Have the P/Ps been published in a searchable format for easy reference?
8. Is access to P/Ps tracked to understand which ones are attracting more attention?
9. Who has been responsible for integrating policies and procedures?
10. Have the policies been rolled out in a way that ensures employees' understanding of them?
11. What steps have been taken by the company to ensure that P/Ps have been integrated into the organization, including through periodic training and certification for all directors, officers, relevant employees, and, where appropriate, agents and business partners?
12. What resources were available to employees to provide guidance relating to compliance P/Ps?
13. Are there policies and procedures that set forth appropriate disciplinary measures for engaging in criminal conduct and for failing to take reasonable steps to prevent or detect criminal conduct?
14. How often has the company updated and reviewed its compliance P/Ps and practices?

FINDINGS

Summary. CCH maintains a Code that discusses compliance related topics, including the duty to report compliance issues, exclusion screening, and fraud, waste, and abuse laws. The Code is reviewed and updated every few years and is dated accordingly. The Code is provided to new workforce members

during new hire orientation and is reviewed annually through the Code of Ethics module of the annual compliance training.

CCH also maintains numerous compliance related policies and procedures. The policies and procedures are regularly reviewed and have a uniformed format.

The following are the detailed key comments/findings related to written guidance:

Code of Ethics

1. CCH maintains a Code that provides an overview of various topics including fraud, waste, and abuse, exclusion screening, and the duty to report violations and non-retaliation.
2. The Code also instructs employees on avenues to report compliance concerns, including the compliance Hot Line and online reporting portal.
3. The Code states that *“failure to comply with the standards established and outlined by this Code of Ethics or to cooperate with CCH leadership regarding activities related to this Code may subject individuals to disciplinary action up to and including discharge of employment or termination of the written contract.”*
4. The Code was last updated in January 2019.
5. There is no introductory letter from the CEO articulating his support and expectations with regard to the compliance program.
6. The Code is provided to new workforce members during new hire orientation. Workforce members review the Code on an annual basis during the Code of Ethics training module as part of the annual compliance training.
7. As part of the training module workforce members must agree to the following certification; *“I understand that I must act in an honest and ethical manner. I recognize that I must comply with all laws, regulations, and CCH policies. I understand that I am obligated to prevent, detect, and report violations of our Code of Ethics. I will comply with the CCH Code of Ethics, the Cook County Ethics Ordinance, CCH policies, and laws and regulations.”*
8. Strategic Management requested additional documentation from CCH to validate that new workforce members receive the Code during orientation and current workforce members review the Code material annually. Strategic Management took a sample of five random new employees and five random current employees to validate receipt of the Code. All five new employees received the Code, and all five current employees completed the Code training during their annual training according to documentation provided.

Policies and Procedures

1. CCH has a *System-Wide Policy Management* policy and procedure that outlines the process for creation, approval, and distribution of CCH policies. The policy states that the Policy Steering

Committee evaluates and approves new and existing policies related to several clinical and administrative areas, including compliance. The “Approval Party” will also consult with the Policy Steering Committee on the additional individuals or committees who should review and approve a policy. According to the *System-Wide Policy Management* policy the CEO has final approval authority over all CCH policies.

2. The *System-Wide Policy Management* policy states that all policies must be reviewed every three years, or more frequently as necessary. Although the compliance policies currently follow this three-year review timeline, upon review of policy revision history there have been indications that prior revisions to the *Excluded Provider Sanction Screening Policy* and *Compliance Audit and Monitoring Policy* did not follow this three year timeline. Compliance should continue to monitor policy review and revisions to ensure it continues to follow the timeline consistent with the *System-Wide Policy Management* policy.
3. For each policy there is a Policy Lead(s) and a Policy Coordinator/Moderator(s). The Policy Lead is responsible for: proposing new policies or revisions to policies; circulating draft policies; attending Policy Steering Committee meetings to present policies; preparing final drafts; communicating to appropriate management the change in policy; and notifying the Policy Coordinator/Moderator that the policy can be posted on the intranet.
4. An organizational Policy Coordinator is also responsible for: monitoring existing policies to ensure they are reviewed on time; assuring appropriate formatting; maintaining the CCH Policy Steering Committee SharePoint site; uploading policies to the intranet; running monthly reports of policies for Policy Steering Committee; and submitting periodic status reports to senior leadership. However, the Compliance Office maintains its own policy matrix which it monitors regularly.
5. All Corporate Compliance and HIPAA Privacy policies, both current and archived, are maintained on a department shared drive with final current policies transitioned through the Policy Committee and maintained on the CCH Intranet.
6. Policy Leads and Operational Managers are responsible for identifying any communication and/or training that must be implemented prior to release of a new or updated policy. This could include either hands on implementation such as training, in-house instruction, or demonstration, or it could include read only implementation or no formal communication or training.
7. CCH has a comprehensive set of compliance and HIPAA policies. The Compliance Office maintains compliance policies and procedures on:
 - Compliance Auditing and Monitoring;
 - Fraud, Waste, and Abuse Reporting;
 - Compliance Program Hotline Reporting;
 - Corporate Compliance Investigations;
 - Excluded Provider Sanction Screening;
 - Corporate Compliance Reporting to the Governance Authorities;
 - Conflict of Interest;
 - False Claims Act and Whistleblower Protections; and
 - Adjudication of Incorrect Claims Payments.

8. All the policies and procedures are formatted uniformly and include a subject, title, policy #, approval date, effective date, purpose, affected areas, definitions, policy, procedure, cross references, and relevant regulatory or other references.
9. The policies state that they are updated every three years. Each policy has a policy history that documents the date(s) the policy was written, reviewed/revised, approved, and posted. The policy history also references old or archived policies on similar subjects.

RECOMMENDATIONS/SUGGESTIONS

Key suggestions that management should consider are summarized as follows:

Code of Conduct

1. The CCH Code should include a letter from the CEO that clearly states his support for the compliance program and ethical behavior, the expectation that all those employed or associated with CCH are expected to follow laws, rules, regulations, and policies relative to the organization, that the program applies equally to everyone and the management team is expected to lead the way with regard to compliance. With the hiring of a new CEO this would be an opportune for him to cogently add his support to the program.
2. The Code should be reviewed more frequently, annually, or bi-annually. This is a common practice in the industry and is called for by both the DOJ and OIG.

Policies and Procedures

3. Strategic Management suggests consideration be given to adding the following compliance program-related policies:
 - **Non-Retaliation Policy.** It is critical that anyone reporting a potential problem can do so without fear of retribution or reprisal. The OIG, DOJ, and U.S. Sentencing Commission all stress the importance of having such a policy as part of an effective compliance program. While currently incorporated into two policies, the Fraud, Waste and Abuse Reporting and Non-Retaliation policy (CC.002.01) and the False Claims Act and Whistleblower Protections policy (CC.008.01), it is recommended that a standalone Non-Retaliation Policy be developed and implemented that clearly sets forth the responsibilities of employees and management to adhere to such a policy as part of a successful Compliance Program.
 - **Anonymous Reporting Policy.** Similarly, while a Compliance Program Hot Line Reporting policy exists, a standalone policy should be implemented. This should reinforce the ability to report matters on an anonymous basis. Having a policy on this topic is stressed by the U.S. Sentencing Commission, OIG, and DOJ.
 - **Confidentiality Policy.** The Code does not specifically provide assurance that identity for those that report problems will be kept confidential, except where identity is required by law. Compliance information received by the Compliance Office and Hotline needs to be kept confidential to the extent that confidentiality is possible throughout any resulting

investigation. The OIG and DOJ singles out and stresses a policy to guarantee confidentiality to those reporting wrongdoings. While confidentiality is noted in multiple policies, this topic warrants a separate stand-alone policy on the subject that extends to all CCH staff who may have access to a reporting individual's identity. All employees must understand that circumstances may arise in which it is necessary or appropriate to disclose information. In such cases, disclosure will be on a 'need to know' basis only.

- **Policy for Coordination with Human Resources (HR).** The great majority of hotline complaints and allegations will include human resources (HR) issues. As such, it is a best practice to have protocols between HR and the Compliance Office in the form of a policy document.
 - **Policy for Coordination with Legal Counsel.** Clarification of respective roles is an important matter as this has been and continues to be a sensitive issue for the government. There have been numerous public statements on this subject by the DOJ and OIG. The concern is that legal counsel may impair the independence of the Compliance Office.
 - **Performance Evaluation of Compliance Policy.** This is specifically called for in the OIG compliance guidance. It should require adherence to the Code and compliance program related policies as part of performance evaluation of managers and employees. The Chief Compliance Officer, Compliance Committee and Human Resources should work to develop and implement a policy with procedures to ensure that performance reviews and evaluations for employees, supervisors and managers include adherence to the Code and all applicable laws, regulations, and policies, as well as compliance training attendance.
 - **Responding to Subpoenas and Requests for Information.** Government oversight agencies have a right to access to information as condition of participation in Medicare and Medicaid, but most often these are in connection with audits and evaluations. There are several types of subpoenas; Civil Demand (tort litigation cases), Administrative (used by the OIG), Civil Fraud (federally issued by U.S. Magistrates), and Grand Jury (in criminal cases). These are demands for documents, records and evidence that must be produced in a set time frame. How they are handled varies by type. There are also difference whether the records being requested are in matters in which CCH is a party, or when that is not the case. A policy outlining the process to be followed in responding to such requests for information should be developed. It should be coordinated with the Legal Department.
 - **Search Warrant Policy.** Unlike demands for evidence, Search Warrants are issued by judges and give government agents the right to control defined areas to seek desired evidence. This is entirely different and more sensitive matter. In such cases the notifications should be far more elaborate. In fact, there should be immediate notification of the most senior person in the entity, Legal Counsel, and others. The step-by-step procedures that need to be followed should be carefully defined in detail to avoid aggravating matters.
4. The Compliance Office should verify that all compliance policies are reviewed and approved on at least a three-year cycle as called for in the *System-Wide Policy Management* policy.

3. COMPLIANCE EDUCATION AND TRAINING

Guidance:

The OIG recommends that hospitals periodically educate employees, including corporate officers, managers, physicians, and other health care professionals, as a significant element of an effective compliance program. Specifically, the education should include *“appropriate training in Federal and State statutes, regulations and guidelines, and the policies of private payors, and training in corporate ethics, which emphasizes the organization’s commitment to compliance with these legal requirements and policies. These training sessions should include material focusing on the organization’s compliance program summarizing fraud and abuse laws, coding requirements, claim development and submission processes and marketing practices that reflect current legal and program standards. Organizations are also responsible for the continual training of current personnel at all levels.”*

The OIG also recommends that *“attendance and participation in training programs be made a condition of continued employment and that failure to comply with training requirements should result in disciplinary action, including possible termination, when such failure is serious. Adherence to the provisions of the compliance program, such as training requirements, should be a factor in the annual evaluation of each employee.”*

Various teaching methods, such as interactive or online training, should be implemented so that all covered employees are knowledgeable of the organization’s standards of conduct and *procedures for informing senior management of problems and concerns.*

The DOJ Guidelines asks many questions about compliance education and training including:

1. *What, if any, guidance, and training has been provided to those with approval authority or certification responsibilities?*
2. *Is information provided during training in a manner tailored to the audience’s size, sophistication, or subject matter expertise?*
3. *Does compliance training include practical advice or case studies to address real-life scenarios, and/or guidance on how to obtain ethics advice on a case-by-case basis as needs arise?*
4. *Are there shorter, more targeted training sessions to enable employees to timely identify and raise issues to appropriate compliance, internal audit, or other risk management functions?*
5. *Does training adequately cover prior compliance incidents and how the company measures the effectiveness of its training curriculum?*
6. *Is the existence and operation of the compliance program being disseminated to, and understood by, employees in practice to decide whether the compliance program is “truly effective”?*
7. *What specialized training have employees in relevant control functions?*
8. *Has the company provided tailored training for high-risk and control employees, including training that addresses risks in the area where the misconduct occurred?*
9. *Have supervisory employees received different or supplementary training?*
10. *What analysis has been undertaken to determine who should be trained and on what subjects?*
11. *Has the training been offered in the form and language appropriate for the audience?*
12. *Is the training provided online or in- person (or both), and what is the rationale for its choice?*
13. *Has the training addressed lessons learned from prior compliance incidents?*
14. *Whether online or in- person, is there a process by which employees can ask questions arising out of the trainings?*

15. How has the company measured the effectiveness of the training?
16. Have employees been tested on what they have learned?
17. How has the company addressed employees who fail all or a portion of the testing?
18. Has there been evaluation of extent training has an impact on employee behavior or operations?

FINDINGS

Summary. CCH requires all new workforce members to receive compliance training during new hire orientation. CCH workforce members must also take annual compliance training that includes three different modules covering the Code, Fraud, Waste, and Abuse laws, and privacy. Each module has a quiz at the end. Eighty percent is passing. Many workforce members reported that the compliance training was sufficient, but it has not changed in a while, so they skip the content to go to the quiz. The Board members also receives education from the Chief Compliance Officer periodically, in addition to the annual compliance training. It was reported that the workforce is usually in compliance with the annual training requirements; no senior staff members reported issues with their direct reports completing training.

The following are key comments/findings related to compliance training:

1. The CCH Human Resources Department has a “Mandatory Training Requirements” policy that outlines the training requirements for CCH employees and staff. The policy outlines the types of training that will be performed and how training will be created and tracked.
2. The policy and interviews confirmed that CCH workforce members receive mandatory compliance training called “Introduction to Corporate Compliance and HIPAA,” during new employee orientation. New employee orientation is held bi-weekly for both new employees and contractors.
3. The “Mandatory Training Requirements” policy states that new CCH workforce members will complete training requirements within 60 days of their start date. This orientation used to be conducted live, including compliance training. However, over the last year due to the COVID-19 pandemic new employee training is conducted through the learning management system (LMS).
4. The “Mandatory Training Requirements” policy states that *“new workforce members are both regulatory and contractually required to complete the Corporate Compliance, CCH Code of Ethics, HIPAA Privacy/Security, and Fraud, Waste, and Abuse training and any other identified courses within 60 days.”*
5. The “Mandatory Training Requirements” policy also states that employees who fail to complete training within the designated timeframe will be subject to disciplinary action.
6. CCH also requires workforce members to take Annual Compliance Training. The Annual Compliance Training is administered through the LMS. The Chief Compliance Officer has administrative access to the LMS and can track completion rates of the Annual Compliance Training.
7. There are three Compliance related modules on the topics of Fraud, Waste, and Abuse, Code of Ethics, and Privacy.
8. The Fraud, Waste, and Abuse training includes information on:

- Definitions of fraud, waste, and abuse;
 - Laws related to fraud, waste, and abuse including the False Claims Act, Anti-Kickback Statute, and Stark Law;
 - Examples of each fraud and abuse law;
 - Exclusion Screening;
 - Health Insurance Portability and Accountability Act (HIPAA);
 - Whistleblowers;
 - Reporting compliance issues, including information related to the hotline; and
 - Corrective actions.
9. The Code of Ethics training includes information on:
- The responsibility to follow the Code;
 - The five sections of the Code;
 - Quality of Care;
 - Conflict of Interest;
 - Patient Privacy and Confidentiality;
 - Accurate Books and Records;
 - False Claims; and
 - Reporting and Non-Retaliation.
10. The Code of Ethics training has a certification at the end of that training, where the trainee must certify that they understand the Code, will comply with the Code and regulations or laws, and understand that they must report issues.
11. The HIPAA Privacy training includes information on:
- Examples of protected health information (PHI);
 - Use and Disclosure;
 - PHI and Public Health Reports;
 - HIPAA Privacy Breach;
 - Computer and Email Security; and
 - HIPAA Sanctions Policy.
12. Each module has a ten-question quiz at the end of the section. However, workforce members can skip the training material and go right to the quiz. Workforce members must receive an 80 percent or higher on the quiz to pass.
13. The quiz questions are simple true/false questions or multiple-choice questions about the material in the training. These questions would not be challenging for anyone who has received compliance training before and likely would not be a very effective test of retention of compliance concepts.
14. Workforce members stated that the training was adequate and thought it was informative overall. However, some interviewees state that it might not be very effective because it does not change greatly from year-to-year and they often skip directly to the quiz.
15. Overall, interviews indicated that there are no issues with completion of mandatory training.

16. The Compliance Office provides in its *2020 Health System Compliance Annual Report* that it works with departments to provide targeted refresher training when a department leader requests the training, or a HIPAA breach occurs. Due to COVID-19 restrictions, refresher training is currently conducted through written guidance.
17. The Compliance Office outlines in the *2020 CountyCare Compliance Annual Report* that it administers provider fraud, waste, and abuse training for new employees or contractors within the plan. The training includes material related to Program Integrity contract changes and an introduction to the compliance program as it relates to CountyCare. The Compliance Office also provided targeted training related to new MCCN Amendments and requirements related to HIPAA and 42 CFR Part 2.
18. CCH requires in its contract terms that contractors receive training as necessary to perform their responsibilities, including compliance and Code training both upon hire and at least annually.
19. The Board of Directors take the same annual compliance training as the rest of the workforce. The Audit and Compliance Committee to the Board of Directors also received some training from the Chief Compliance Officer. The Chief Compliance Officer asks the Committee members questions related to compliance and their responsibilities. The Board of Directors would benefit from receiving additional training on their oversight responsibilities as it pertains to compliance.
20. Strategic Management requested additional documentation from CCH to validate that new workforce members receive training and current workforce members receive annual compliance training. Strategic Management took a sample of five random new employees and five random current employees to validate receipt of compliance training. All five new workforce members received training and all five current workforce members completed the annual training according to documentation provided.

RECOMMENDATIONS/SUGGESTIONS

Key suggestions that management should consider are summarized as follows:

1. CCH compliance education and training material should be periodically updated and refreshed to ensure the material is current with laws, regulations, and industry standards. It also has the benefit of providing new updated information that will help keep workforce paying attention to the lessons provided. Many interviewees stated that they skip the content of the training to take the test. If the training is updated with new material periodically workforce members may be less inclined to skip the content of the training. Some updates that could be made to the training are situation-based scenario examples and information about state specific fraud, waste, and abuse laws. Compliance may also want to add to their training, materials explaining what issues should be reported to compliance versus legal versus operational leads, this will help to improve workforce member's knowledge on the scope of compliance's responsibilities. Compliance may benefit from using a creative adult education expert to provide expertise on the best ways to enhance compliance training.
2. CCH should consider enhancing its compliance training question process to include scenario-based questions related to their work situations. Scenario based questions will allow training to be more impactful and allow workforce members to better understand how compliance impacts operations.

This will allow Compliance to refresh training more often and keep workforce members engaged, especially those workforce members who have taken the training multiple times.

3. Although the Compliance Office does provide ad-hoc training as part of CAPs and at the request of managers, most workforce members only receive training during orientation and annual training. In order to increase compliance knowledge of the workforce members and provide increased compliance visibility, the Compliance Office could create and distribute compliance newsletters or other educational materials. The newsletters can include compliance tips and news stories that highlight compliance topics or provide a deeper dive into specific topics. Again, this will allow the Compliance Office to have another touchpoint with workforce members that would not be related to investigations or CAPs. It would also provide workforce members with a greater understanding of the scope of Compliance Office's responsibilities.
4. The Compliance Office may want to consider alternative training strategies. While on-line learning may be more efficient and expedient, the Compliance Officer may want to explore ways in which training can be delivered in a manner that is more conducive to learning. This is not to suggest that on-line programs are not an effective and efficient method of training; however, different people learn differently. One possibility would be to put some of the onus on managers to deliver key compliance messages directly to their people. This would have several benefits—first compliance messages could be tailored to their specific work and areas of risk, and second, requiring managers to develop training may further their own education, support and understanding of the compliance program and how important they are in determining its success.
5. The Chief Compliance Officer could provide additional periodic compliance training to the Board of Directors. The training should review topics related to the Board's oversight responsibilities as emphasized in HHS OIG Compliance Program Guidance, DOJ Evaluation of Compliance Programs materials, and materials from professional compliance and health care organizations. The training should also provide an overview of regulatory risks and changes that could impact CCH.

4. COMPLIANCE LINES OF COMMUNICATION

Guidance:

At a minimum, the OIG recommends *“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.”*

Open lines of communication between the Chief Compliance Officer and employees are essential to the success of an organization's compliance program, including the reduction of potential for fraud, abuse, and waste. The establishment of alternative independent reporting paths for employees to report wrongdoing, such as through hotlines, e-mails, written memoranda, newsletters, and other forms of information exchange, can help maintain open lines of communication.

The Compliance Office should be structured in such a way that employees will feel comfortable approaching the Chief Compliance Officer with problems and have faith that their concerns will be handled promptly and thoroughly. The organization should document its confidentiality and non-retaliation policies and procedures, as the OIG believes that employees or others who report incidences of fraud or abuse should be protected from retribution.

In “*Practical Guidance for Health Care Governing Boards on Compliance Oversight*” the OIG comments; “As an extension of their oversight of reporting mechanisms and structures, Boards would also be well served by evaluating whether compliance systems and processes encourage effective communication across the organizations and whether employees feel confident that raising compliance concerns, questions, or complaints will result in meaningful inquiry without retaliation or retribution. Further, the Board should request and receive sufficient information to evaluate the appropriateness of management’s responses to identified violations of the organization’s policies or Federal or State laws.”

The DOJ “*Compliance Program Evaluation of Effectiveness Guidelines*” focuses considerable attention on compliance communication, including asking the following questions of organizations:

1. Are employees able to report allegations of a breach of the company’s code of conduct, company policies, or suspected or actual misconduct, anonymously or confidentially?
2. What evidence is there that the company’s complaint-handling process includes proactive measures to create a workplace atmosphere without fear of retaliation, appropriate processes for the submission of complaints, and processes to protect whistleblowers?
3. What are the processes for routing of complaints to proper personnel for investigation?
4. Are investigations of complaints thoroughly investigated in a timely manner?
5. Are investigative findings resulting in appropriate follow-up and discipline?
6. Does the company compliance program have in place and publicized a system that allows for anonymity or confidentiality, whereby the employees and agents may report or seek guidance regarding potential or actual criminal conduct without fear of retaliation?
7. Does the company have an anonymous reporting mechanism and, if not, why not?
8. How is the reporting mechanism publicized to employees and other third parties?
9. Have there been reports received from employees?
10. How is information from reporting mechanisms collected, tracked, analyzed, and used?
11. Is there periodically testing of the hotline effectiveness (e.g., tracking a report from start to finish)?

FINDINGS

Summary. CCH has multiple lines of communication that workforce members can use to report compliance issues or possible violations, including a Hot Line and an online reporting portal. The duty to report and mechanisms for reporting are emphasized in the Code and the compliance training. Workforce members who were interviewed were aware of their duty to report. The Compliance Office tracks items reported through the various lines of communication and reports the number of compliance contacts to the Audit and Compliance Committee and the Compliance Steering Committee. Some workforce members also use the eMERs system to report HIPAA and compliance issues, which may lead to a delay in the Compliance Office receiving such items or indicate that workforce members are not sure when to use the Hot Line.

The Code, “Compliance Program Hot Line Reporting” policy, and training all emphasize that CCH has a non-retaliation policy.

The Compliance Office reportedly communicates well with other departments, especially other members of senior leadership. However, some interviewees expressed that it would be helpful for Compliance to

better communicate the scope of their duties, as it can be hard to know which department to bring issue to, even if they are unsure if it is a compliance matter.

The following are key comments/findings related to lines of communication:

1. CCH provides multiple channels for workforce members to report concerns or ask questions related to compliance. Workforce members can communicate concerns to:
 - Their supervisor;
 - Confidential Hot Line or online reporting portal; or
 - The Compliance Office through an email or letter.
2. The reporting channels are available in the Code, Compliance training, and the “Compliance Program Hot Line Reporting” policy. The Compliance Office has also used screen savers that explained how to contact compliance.
3. The Compliance Hot Line is available 24/7 for 365 days a year. The Compliance Hot Line is administered through a third-party vendor, Navex Global. Workforce members can report issues and concerns anonymously.
4. The Compliance Office has a “Compliance Program Hot Line Reporting” policy that states, *“CCH will establish and maintain a telephone hot line, known as the Corporate Compliance Hot Line that CCH workforce members and other interested parties may use to report problems and concerns either anonymously or in confidence.”*
5. The “Compliance Program Hot Line Reporting” policy also states, *“CCH workforce members are strongly encouraged to report problems and concerns via the chain-of-command before resorting to the Corporate Compliance Hot Line.”*
6. Workforce members can also report issues through an EthicsPoint website. The EthicsPoint webpage reiterates that workforce members have a duty to report, that the Hot Line is 24/7, and the importance of compliance reporting.
7. CCH also provided an example of a Hot Line report produced by the EthicsPoint system. The report provides information on the organization subject to the report, a summary of the reported issue, the reporter’s contact information, and additional notes from the reporter. It also contains a summary of a follow-up to the reporter.
8. The Compliance Office tracks reported contacts, through a compliance issue reporting and tracking tool - developed using Salesforce. The tool provides dashboards and generates the excel spreadsheet report (where needed). The tool enables compliance to produce reports, easily customizable for what is needed, and provides active reminders where cases are past a due date or have not yet been closed. The tool also tracks resolution of issues, indicating whether the issue was substantiated, when it was resolved, and what action was taken to resolve the issue.
9. The “Compliance Program Hot Line Reporting” policy states that *“CCH workforce members who report problems and concerns via the Corporate Compliance Hot Line in good faith will be protected from any form of retaliation or retribution, and any employee who commits or condones any form of retaliation*

will be subject to discipline up to and including termination.” However, CCH does not have a separate non-retaliation policy.

10. During interviews, many workforce members also reported that they use the eMERS system to report issues, they often mentioned reporting HIPAA specific issues in the eMERS system.
11. The Compliance Office reports numbers of reported compliance contacts to the Committees. The numbers of calls, along with commentary from interviewees provide confirmation that the Hot Line is utilized. Individuals also expressed that workforce members generally feel comfortable reporting issues.
12. No one reported a fear of retaliation.
13. Interviewees who worked directly with the Compliance Office on reported issues or compliance related questions stated that compliance responded quickly and communicated well on resolving issues or answering questions.
14. Compliance is responsible for triaging issues reported through the Hot Line and will notify Human Resources or other departments if an issue that has been reported falls under their responsibilities.

RECOMMENDATIONS/SUGGESTIONS

Key suggestions that management should consider are summarized as follows:

1. Corporate Compliance should adopt a separate, standalone Non-Retaliation policy. Although non-retaliation is discussed in the “Compliance Program Hot Line Reporting”, it should be emphasized through its own policy, because having such a policy is stressed by both the DOJ and OIG.
2. Compliance in partnership with the Quality and Patient Safety Department should provide education on what issues should be reported in the eMERS system and what should be reported to the Hot Line. Many interviewees stated that they report issues in the eMERS system but did not specifically mention the Hot Line. Compliance, along with other appropriate departments should provide education to ensure that issues are being reported through the appropriate channel.
3. While no-one reported a fear of retaliation for reporting an issue or problem, none-the-less this issue must continue to be an area of focus, principally because it is always an underlying or at least a potential problem. It is important not only for the Compliance Office to reinforce the non-retaliation message but also operating managers, because that is where issues start and that is where many issues can and should be resolved. The fact is managers must understand the need to create a positive and nurturing environment where employees are comfortable asking questions or disclosing issues.

5. COMPLIANCE ENFORCEMENT/SANCTION SCREENING

Guidance:

The OIG guidance provides that *“at a minimum, comprehensive compliance programs should include... 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. With regard to sanction screening the guidance states; "Pursuant to the compliance program, hospital policies should prohibit the employment of individuals who have been recently convicted of a criminal offense related to health care or who are listed as debarred, excluded or otherwise ineligible for participation in Federal health care programs...Likewise, hospital compliance programs should establish standards prohibiting the execution of contracts with companies that have been recently convicted of a criminal offense related to health care or that are listed by a Federal agency as debarred, excluded, or otherwise ineligible for participation in Federal health care programs."

According to the OIG, an effective compliance program should include guidance regarding disciplinary action for corporate officers, managers, employees, physicians, and other health care professionals who have failed to comply with the organization's code, policies and procedures, or federal and state laws, or those who have otherwise engaged in wrongdoing that has the potential to jeopardize the organization's reputation as a reliable, honest, and trustworthy health care provider.

All levels of employees should be subject to the same disciplinary action for the commission of similar offenses. Corporate officers, managers, supervisors, medical staff, and other health care professionals should be held accountable for failing to comply with, or for the foreseeable failure of their subordinates to adhere to, the applicable standards, laws, and procedures. Compliance should be an element of performance appraisal for all employees.

The OIG recommends for all new employees who have discretionary authority to make decisions that may involve compliance with the law or compliance oversight, health care organizations should be subject to a reasonable and prudent background investigation, including a reference check, as part of every such employment decision. Employment applications should specifically require applicants to disclose any criminal conviction or exclusions.

The OIG has published considerable guidance with respect to sanction screening. In its *"Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs"* issued May 8, 2013, the OIG states, *"The effect of an OIG exclusion is that no Federal health care program payment may be made for any items or services furnished (1) by an excluded person or (2) at the medical direction or on the prescription of an excluded person. The exclusion and the payment prohibition continue to apply to an individual even if he or she changes from one health care profession to another while excluded. This payment prohibition applies to all methods of Federal health care program payment, whether from itemized claims, cost reports, fee schedules, capitated payments, a prospective payment system or other bundled payment, or other payment system and applies even if the payment is made to a State agency or a person that is not excluded."* The OIG expects that sanction screening should at a minimum be done against its List of Excluded Individuals and Entities (LEIE).

The DOJ Guidelines also focuses on this area in their evaluations by asking several specific questions, including:

1. *Are there similar instances of misconduct that were treated disparately, and if so, why?*
2. *Is there established means of documenting any disciplinary or remediation measures taken?*
3. *Has the company taken any remedial actions, including disciplinary action against past violators uncovered by the prior compliance program?*
4. *Has there been appropriate discipline of employees, identified as responsible for the misconduct,*

either through direct participation or failure in oversight, as well as those with supervisory authority over the area in which the criminal conduct occurred?

5. *What disciplinary actions were taken in response to the misconduct, and was it timely?*
6. *Were managers held accountable for misconduct that occurred under their supervision? Did the company consider disciplinary actions for failures in supervision?*
7. *What is the company's record (e.g., number and types of disciplinary actions) on employee discipline relating to the types of conduct at issue?*

FINDINGS

Summary. CCH has disciplinary policies and procedures that formalize the disciplinary actions CCH can take in response to violations of its policies, procedures, regulations, and legal requirements. Human Resources administers the disciplinary policy and works with operational leads to implement necessary disciplinary action. Following a compliance investigation, if the Compliance Office finds that a disciplinary action may be appropriate it will make a recommendation to Human Resources and Human Resources, along with the appropriate supervisor will implement the disciplinary action. The Compliance Office also has a separate sanctions policy for HIPAA related violations.

CCH conducts exclusion screenings on all new workforce members and vendors prior to hire or contract to ensure they have not been excluded from state and federal health care programs. The Compliance Office also conducts exclusion screening on a monthly basis for all current workforce members and vendors. This is formalized in the Compliance Office's "Excluded Provider Sanction Screening" policy.

The following are key comments/findings about this area:

1. It was expressed through multiple interviews that CCH has a complicated and detailed disciplinary process that Human Resources implements and manages. The disciplinary steps are progressive in nature and include re-education, verbal warnings, written warnings, suspension, and termination. However, the progressive nature of CCH disciplinary policy will not prevent a more severe form of discipline for a more serious violation of CCH rules of conduct.
2. The CCH "Conduct and Discipline of Personnel" policy is in the CCH Personnel Rules. The disciplinary policy outlines what CCH considers "major cause" infractions that can lead to a higher level of discipline immediately and "non-major cause" infractions that will lead to lesser levels of discipline. The policy also provides a detailed description of what factors will be considered when deciding disciplinary action and the different levels of disciplinary actions. Finally, the policy outlines the procedures for imposing disciplinary action.
3. There is a joint Human Resource and Compliance policy that establishes sanctions for HIPAA violations. The "Sanctions: HIPAA Privacy and Security Breaches" policy outlines the different steps that will be taken to investigate a possible HIPAA violation. It also provides that disciplinary action will be recommended based on the severity of the violation and the intent behind the violation. The policy states that an unintentional failure to follow HIPAA policies and procedure may lead to written reprimand and retraining, suspension and retraining, and termination/severance of relationship with CCH. The policy also states that intentional, deliberate, or purposeful failure to follow HIPAA policies and procedures can lead to suspension and retraining or termination.

4. Human Resources confirmed that when the Compliance Office investigates a compliance issue and recommends a disciplinary action, they will provide the findings to Human Resources and the manager of the impacted unit. The manager will be responsible for implementing the disciplinary action and documenting the disciplinary action.
5. Multiple interviewees expressed that disciplinary action can be difficult to implement at CCH. Some workforce members expressed that disciplinary actions were difficult because of the formal procedures that must be followed to implement disciplinary action. However, others expressed that disciplinary action is not difficult to implement due to the formalities, but just takes more time.
6. The Compliance Office has an “Excluded Provider Sanction Screening” policy. The policy provides that CCH will screen all workforce members and vendors against the General Service Administration (GSA) System for Award Management (SAM), Office of Inspector General (OIG) List of Excluded Individuals/Entities (LEIE), Illinois Department of Healthcare and Family Services (HFS) List of Terminated/Suspended Providers and Barred Individuals, and Office of Foreign Assets Controls (OFAC) List of Specially Designated Nations (SDN).
7. The policy states that Human Resources is responsible for screening applicants, employees, and volunteers. Human Resources confirmed during interviews that they conduct extensive background checks on any applicants, which includes sanction screening.
8. The policy states the CCH Medical Staff Services Department is responsible from checking Medical Staff and Allied HealthCare Staff employees, volunteers, and consultants against sanction screening lists.
9. According to the “Excluded Provider Sanction Screening” policy, Supply Chain Management is responsible for screening vendors. Interviews with the Procurement Department confirmed that it conducts initial vendor screening, and screening is conducted annually when required for external audits, but that Compliance Office does monthly screening of vendors. This process could be clarified further to ensure the policy and actual implementation of screening are consistent. The policy also does not specify what steps will be taken if a contractor is already engaged and comes back as excluded.
10. The “Excluded Provider Sanction Screening” policy states that CCH Managed Care/CountyCare staff is responsible for screening all current and prospective CountyCare contractors and subcontractors prior to engaging in the contract. The policy also states that the contractors will be screened on a monthly basis.
11. The Policy also states that the Compliance Office is responsible for conducting monthly screenings for employees, contractors, and volunteers.
12. CCH utilizes a third-party, John Sterling Associates to conduct monthly screening of its vendors and workforce members. The “Excluded Provider Sanction Screening” policy does not mention the use of John Sterling Associates.

13. The Compliance Office provided emails that indicated there is difficulty including complete information regarding vendors which makes it harder to screen these vendors and confirm potential matches.
14. The Compliance Office also provided information that a recent new hire was not flagged by the initial exclusion screening and was only discovered as excluded after the individual's first monthly screening. Once it was discovered that the individual was excluded the individual was immediately terminated. It was noted that this occurred during a push to hire people as COVID contact tracers.
15. The Compliance Office recently conducted an audit of the Human Resources Department and its exclusion/sanction process and documentation. The Department was unable to provide authoritative source documentation as proof of sanction checks, so a CAP has been put in place to mitigate the issue.
16. The employment application for CCH ask questions of applicants related to their license and any criminal background, but it does not ask if an applicant has been excluded from federal or state health care programs.
17. Strategic Management requested additional documentation from CHHS to validate that employees are screened against the LEIE and other exclusion lists. Strategic Management took a random sample of five new workforce members and random sample of six existing workforce members to verify that they were screened prior to initial hire and to verify that they were screened monthly in accordance with CCH policy. Strategic Management requested that CCH provide the monthly screenings for May 2020 and December 2020. All five new workforce members were screened upon hire and prior to their start date. Five of the six employees selected were screened in May 2020 and December 2020. The sixth employee was hired in December 2020, and records show that he was screened in January 2020.
18. Strategic Management requested additional documentation from CCH to validate that vendors are screened against the LEIE and other exclusion lists. Strategic Management took a random sample of five new vendors and a random sample of five existing vendors to verify that they were screened prior to initial contracting and to verify that they were screened monthly in accordance with CCH policy. Four of the five new vendors were screened prior to start of service, a record for the fifth vendor was not provided. Four of the five existing vendors were screened in May 2020 and December 2020. The Chief Compliance Officer has identified the issue with the fifth vendor and will discuss corrective action with Supply Chain Management to address the issue.

RECOMMENDATIONS/SUGGESTIONS

Key suggestions that management should consider are summarized as follows:

1. CCH should update its "Excluded Provider Sanction Screening" policy to ensure it is clear who will conduct monthly exclusion screenings on vendors and the consequences for a current vendor if it does come back as excluded during monthly screening. All other exclusion screenings are assigned to a specific department, such as Human Resources for new employees, Supply Chain Management for new vendors, and Compliance for current employees, but it does not specify who will be responsible for screening current vendors.

2. CCH should update its “Excluded Provider Sanction Screening” policy to include information indicating it uses a third-party vendor to conduct its monthly exclusion screenings.
3. The Compliance Office provided communication between CCH and its exclusion screening vendor that indicated that CCH did not provide all the necessary information on their vendors for them to be properly screened. CCH should identify what necessary information was missing and ensure that information is collected during any contracting or procurement process of new vendors so they can be adequately screened in the future. CCH should also communicate with existing vendors to ensure they have the necessary information to conduct proper monthly screening.
4. CCH should update its employee application to include questions about exclusion from federal and state health care programs.

6. COMPLIANCE MONITORING AND AUDITING

Guidance:

According to the OIG, the “*use of audits and/or other risk evaluation techniques to monitor compliance and assist in the reduction of identified problems*” is an essential element in a comprehensive Compliance Program. The OIG believes that an effective program should incorporate this element through monitoring of compliance program implementation and regular reporting to senior executives and the Board of Directors. The importance of auditing and monitoring is underscored in the OIG Supplemental Compliance Guidance for Hospitals issued in 2005.

An organization’s auditing and monitoring efforts should consist of two major components: (1) monitoring the effectiveness of the compliance program itself and (2) periodic auditing of risk areas. Both of these monitoring activities should be performed by independent and unimpaired parties.

According to the “*Practical Guidance for Health Care Governing Boards on Compliance Oversight*,” the Board should ensure that management and the Board have strong processes for identifying risk areas. “*Risk areas may be identified from internal or external information sources. For instance, Boards and management may identify regulatory risks from internal sources, such as employee reports to an internal compliance hotline or internal audits. External sources that may be used to identify regulatory risks might include professional organization publications, OIG-issued guidance, consultants, competitors, or news media. When failures or problems in similar organizations are publicized, Board members should ask their own management teams whether there are controls and processes in place to reduce the risk of, and to identify, similar misconduct or issues within their organizations. The Board should ensure that management consistently reviews and audits risk areas, as well as develops, implements, and monitors corrective action plans. One of the reasonable steps an organization is expected to take under the Guidelines is “monitoring and auditing to detect criminal conduct. Audits can pinpoint potential risk factors, identify regulatory or compliance problems, or confirm the effectiveness of compliance controls. Audit results that reflect compliance issues or control deficiencies should be accompanied by corrective action plans.”*”

The DOJ Guidelines also place a focus on this area with many questions, including:

1. *Has the company analyzed and addressed the varying risks presented by, among other factors,*

the location of its operations, the industry sector, the competitiveness of the market, the regulatory landscape, potential clients and business partners, transactions with foreign governments, payments to foreign officials, use of third parties, gifts, travel, and entertainment expenses, and charitable and political donations?

2. *How effective is the company's risk assessment process?*
3. *What methodology has the company used to identify, analyze, and address the risks it faces?*
4. *What information or metrics have been collected and used to help detect high-risk misconduct?*
5. *Is a disproportionate amount of time focused on low-risk areas instead of high-risk areas?*
6. *Is the risk assessment current and subject to periodic review?*
7. *Is there a tracking and incorporating risk assessment lessons learned prior issues?*
8. *Does the compliance program apply risk-based due diligence to its third-party relationships?*
9. *How often does internal audit conduct assessments in high-risk areas?*

FINDINGS

Summary. The CCH Compliance Office identifies and communicates compliance risks through an annual report and a risk assessment, this did not occur in preparation for FY 2021. The Public Health Emergency and limited bandwidth with staffing deficiencies restricted the full functionality of the Compliance Program. However, in FY 2021, a Strengths, Weaknesses, Opportunities, and Threats (SWOT) matrix was developed, primarily for the new CEO and in lieu of a formal risk assessment. The Compliance Office also conducts audits related to identified compliance matters. The audits are often reactive, but the Compliance Office should start conducting more proactive compliance audits. CCH operational departments also conduct monitoring activities at varying levels of frequency, scope, and depth.

The following are key comments/findings about this issue area:

1. The Compliance Office has a "Compliance Auditing and Monitoring" policy. The policy states that CCH will conduct ongoing auditing and monitoring of identified risks, implement systems to audit and monitor departmental compliance with laws and regulations, and maintain a system for tracking auditing and monitoring activities.
2. The Policy states that the Chief Compliance Officer or designee will be responsible for establishing an auditing and monitoring plan, overseeing compliance audit, working with operational units on monitoring, identifying risk areas, assist system leadership with corrective action plans, and overseeing and validating implementation of corrective action plans.
3. The Policy also states that system leadership will conduct compliance monitoring activities.
4. The Compliance Office provides an Annual Report to the Audit and Compliance Committee. In the 2020 Annual Report, the Compliance Office summarizes the auditing and monitoring activities and the risk assessment process for the year.
5. The Annual Report notes that through surveys with executive leadership and key organization leaders, along with consideration of industry risks, and activities from the prior year, the Compliance Office identifies areas of risk. The Compliance Office identified eight risks, which are listed in the Annual Report.

6. In preparation for FY 2021 and the onboarding of a new CEO, the Compliance Office created a Strengths, Weaknesses, Opportunities, and Threats (SWOT) matrix. Some of the weaknesses identified in the matrix were a lack of formal risk assessment and dedicated compliance auditing and monitoring team on the provider side.
7. The Internal Audit Department also creates an annual enterprise-wide work plan. Internal Audit and Compliance Office do work with each other on audits where the department's respective expertise is required. However, the departments do not actively leverage the resources of either department in a proactive way. Compliance will not usually ask Internal Audit to conduct an audit on their behalf. Both departments have limited resources. However, both departments report working well with each other and communicating and collaborating when necessary. The Internal Audit Department and Compliance could leverage the limited resources of each department and work together and simultaneously to create a risk assessment that identifies, among others, compliance risks.
8. The Compliance Office does not have a Risk Assessment Policy or a standalone Audit Resolution Policy.
9. The Annual Report also summarized HIPAA auditing and monitoring that took place in 2020. The Annual Report also noted that CCH engaged an outside auditor to conduct an independent Professional Fee Coding Probe Audit.
10. Following the audit, the Compliance Office worked with Health Information Management (HIM) to implement a CAP to ensure errors found during the audit were corrected and safeguards put in place to decrease similar errors in the future. This collaboration following the Professional Fee Coding Probe Audit was also confirmed through an interview with the HIM Director, who stated that Compliance was a significant help in the creation of the CAP.
11. The Compliance Office, along with other operational leaders, discussed in interviews that Compliance should do more proactive audits. Currently, the Compliance Office conducts many of its audits in response to an identified issue, rather than identified risks that should be proactively mitigated.
12. Multiple operational leads described monitoring activities that they perform for their areas of responsibility, including monitoring and incorporation of regulatory changes, use of automated systems, and quality checks.
13. Audits are tracked in the Salesforce compliance tracking tool. Audit reports can readily be downloaded from Salesforce.
14. It is noteworthy that staff reductions have limited the resources available to conduct "root cause" analysis of all identified compliance-related risk areas, as called for by the DOJ Guidelines, as well as ensuring a robust ongoing auditing program to ensure that compliance risk management and mitigation efforts are fully effective.

RECOMMENDATIONS/SUGGESTIONS

Key suggestions that management should consider are summarized as follows:

1. The Compliance Officer needs to re-institute a comprehensive risk assessment process that involves working with management to identify and assess compliance risks in the organization. The risk assessment process should include not only risk rating but identifying and creating an inventory of existing controls to mitigate each risk. Derivatives of the risk assessment should not only be audits to be conducted but also a management monitoring plan and input to the compliance training plan. It is critical that the Compliance Office and operating management collaborate closely in developing and implementing an effective and comprehensive auditing and monitoring strategy. Operating management must be involved since ongoing monitoring is its responsibility. The goal will be to effect coverage of the universe of risks—in some manner. Reports to oversight committees should not only include the status and results of audits and plans of correction but also the results of management’s monitoring efforts and status of plans of correction. Due to the Compliance Office’s limited staff it can also work with Internal Audit to simultaneously conduct interviews with staff to identify risks and create a risk assessment that includes compliance audits.
2. As noted above, in providing coverage for the universe of relevant compliance risks, department, and program manager monitoring activities must be considered as part of an overall compliance risk monitoring program. While the Compliance Office is responsible for a comprehensive audit and review strategy, fundamentally, management is still responsible for creating effective internal controls in their areas of responsibility, including adequate monitoring mechanisms vis-à-vis pertinent compliance risks. Such monitoring mechanisms should include sampling of transactions to determine whether rules, regulations and standards are being followed. In that vein, sampling guidance should be provided to department or operating managers who are monitoring compliance risks within their own areas of responsibility. A hierarchy of tests should be considered. For example, a manager may begin with a small probe or judgmental sample. If there are *any* hits (i.e., errors) then a larger probe should be taken. If again there are any hits or errors found, then a statistically valid random sample should be considered in accordance with a written protocol defining when these "statistical escalations" should occur. In addition, where an error is identified the manager should determine the reason for the error and whether systemic problems or weaknesses may exist. The Compliance Office and potentially the Legal Department should be contacted.
3. For audits and reviews conducted by Compliance Office staff, plans of correction should be developed by management. The plans of correction should be included in the audit report so the oversight committees can see completely, what was found and how and when issues will be resolved. To that end, the plans of correction should have due dates for each task and the name of the person responsible for completing the task.
4. A stand-alone Audit Resolution Policy that describes requirements and deadlines for plans of correction should be developed by the Compliance Office. Once a risk assessment process is initiated, the Compliance Office should develop a Risk Assessment Policy that describes how the risk assessment will be conducted, how risks will be ranked, and how risk assessment results will be communicated to other departments and senior leadership.

7. RESPONSE TO DETECTED OFFENSES & CORRECTIVE ACTION

Guidance:

The OIG recommends the *“investigation and remediation of identified systemic problems.”* According to the OIG, an organization should take prompt and appropriate action upon receipt of information of

possible wrongdoing to determine whether corrective action measures are needed. This includes the entire investigative and reporting process. As stated in OIG Compliance Guidance, *“Upon reports or reasonable indications of suspected non-compliance, it is important that the chief compliance officer or other management officials initiate prompt steps to determine whether a material violation of applicable laws or requirements of the compliance program has occurred and if so, take steps to correct the problem.”*

The DOJ Guidelines asks a number of questions related to this area, including:

1. *How does the company ensure that investigations are properly scoped?*
2. *What steps does the company take to ensure investigations are independent, objective, appropriately conducted, and properly documented?*
3. *How does the company determine who should investigate, and who makes that determination?*
4. *Does the company apply timing metrics to ensure responsiveness?*
5. *Does the company have a process for monitoring the outcome of investigations and ensuring accountability for the response to any findings or recommendations?*
6. *Are the reporting and investigating mechanisms sufficiently funded?*
7. *Does the company periodically analyze the reports or investigation findings for patterns of misconduct or other red flags for compliance weaknesses?*
8. *Are there legal or investigation-related reasons for restricting information, or have pre-textual reasons been provided to protect the company from whistleblowing or outsiderscrutiny?*
9. *Does the company have a well-functioning and appropriately funded mechanism for the timely and thorough investigations of any allegations or suspicions of misconduct by the company, its employees, or agents?*
10. *How has the company ensured that the investigations have been properly scoped, and were independent, objective, appropriately conducted, and properly documented?*
11. *Have the company’s investigations been used to identify root causes, system vulnerabilities, and accountability lapses, including among supervisory managers and senior executives? What has been the process for responding to investigative findings?*
12. *How high up in the company do investigative findings go?*
13. *Is the company, in practice, able to conduct a thoughtful root cause analysis of misconduct and timely and appropriately remediate to address the root causes?*

FINDINGS

Summary. The CCH Compliance Office conducts compliance investigations in a professional and efficient manner. The Compliance Office is guided by a “Corporate Compliance Investigation” policy. The Compliance Office tracks all investigations. The Compliance Office works with other departments to create and implement CAPs based on investigatory findings.

The following are key comments/findings about this issue area:

1. The Chief Compliance Officer and her staff have the authority to investigate compliance issues. The Chief Compliance Officer job description states that the Chief Compliance Officer duties include responding to alleged violations of rules, regulations, policies, and procedures. Interviews confirmed that the Compliance Office responds to potential violations expediently and works well with operational units and departments to investigation potential violations.

2. The Compliance Office maintains a “Corporate Compliance Investigation” policy. The policy outlines the investigation process, stating that all investigations shall be initiated no later than three business days following receipt and completed within 30 days. The policy provides that the individual coordinating the investigation shall identify all supervisory personal responsible for the area under investigation.
3. The Policy states that the Compliance Office has authority to conduct interviews and review documents, including contracts to conduct the investigation.
4. The Policy outlines specific steps that will be taken to coordinate investigations that may have legal implications, impacted medical claims submitted to government programs, or implicate grant funds.
5. The Policy states that documentation of investigation must include: (1) a description of the nature of the problem; (2) a summary of steps taken during the investigations; (3) recommendations for corrective actions, as appropriate; and (4) a description of any ongoing monitoring necessary to ensure the issue has been corrected.
6. The Compliance Office uses Salesforce to track and monitor compliance issues and investigations, however, it contains information about CAPs that were put in place to resolve issues.
7. The Compliance Office provided two examples of corrective action plans, called Deficiency Action Plan (DAP). The DAP outlines a description of the issue, action plan, action due date, and status. Both DAPs provided were for issues impacting CountyCare.
8. Similar documents for issues in the health system are maintained. The CAP tracking documents contain information on the violated policy, the requirement outlined in the violated policy, the department’s corrective action plan, and the responsible party and completion date.
9. The Compliance Office, along with other members of leadership, expressed concerns with the effectiveness of CAPs, particularly for the health system. Following an investigation and recommendation for corrective action, it is the responsibility of the operational lead overseeing the issue area to create a CAP and implement the corrective actions. The Compliance Office reported concerns that operational units are unresponsive to recommendations from Compliance for corrective actions and often do not take the steps necessary to implement the CAPs.
10. This issue regarding lack of response and implantation of corrective actions has been discussed with the CEO. He has supported the Compliance Office and made it policy that if an operational unit does not respond to a CAP request from Compliance, he should be copied on the next communication and if necessary, escalate it from there.
11. Although some interviewees reported follow-up audits following the implementation of CAPs, this was not found to be consistently reported.
12. According to documentation, investigations results and CAPs are not regularly reported to the oversight committees.

13. With cutbacks in staffing, the Compliance Office is curtailed in the ability to do “root cause” analysis of all identified compliance-related incidents.

RECOMMENDATIONS/SUGGESTIONS

1. The Compliance Office and leadership should work to ensure that CAPs are created and implemented by operational staff. This can be implemented through increased support from executives and vice presidents throughout CCH. There should be a clear message that when a compliance issue has been identified and a corrective action must be implemented that it is the responsibility of the operating department overseeing the function to implement a CAP. Additional education of managers regarding the CAP process and scope of responsibilities can also be used to make these changes.
2. Compliance should follow-up on corrective actions through audits to ensure that the implemented corrective action was effective in mitigating the issue.

CERTIFICATION & VALIDATION REVIEW

Strategic Management certifies it conducted the performance and evaluation review in accordance with the independence and objectivity guidelines of the Generally Accepted Government Audit Standards (GAGAS) of the Government Accountability Office (GAO). Strategic Management work entailed an objective and systematic examination of evidence to provide an independent assessment of the performance and management of the CP against objective criteria drawn from the 2018 Federal Sentencing “Guidelines for Organizations”; the DHHS Office of Inspector General “Compliance Guidance for Hospitals”; and 2019 and 2020 Department of Justice “Compliance Program Effectiveness Evaluation Guidelines”. The individual assigned to perform the independent review possessed the necessary professional proficiency for the tasks required and were free from impairments that hinder objectivity. In performing the review, he exercised due professional care in the review and in preparing the report of findings. All findings will be supported by evidence in the working papers. The review report presents factual data accurately, fairly, and objectively, with findings, determinations, and conclusions presented in a persuasive manner. All recommendations and suggestions included in the report arise from findings, and all findings are supported with documentation maintained in the work papers. The final report underwent a referencing review as part of quality assurance to ensure that all findings arose from the work of Strategic Management and that all recommendations are directly supported by the findings. This final review was conducted by the Strategic Management CEO, Richard P. Kusserow, who previously served 11 years as the DHHS Inspector General.

Strategic Management’s assessment of the BHS Compliance Program effectiveness was led by Steven Forman, CPA, and Strategic Management Senior Vice President, who has over 25 years’ experience in healthcare compliance. This includes having worked in the Department of Health and Human Services OIG, providing CP consulting services for over 18 years, and serving as the Vice President for Internal Audit and Corporate Compliance at New York-Presbyterian Hospital for 10 years (retired at the end of 2011). During his consulting career, he has built and evaluated over 50 CPs for a full range of healthcare providers. Mr. Forman also underwent an in-depth training on the Strategic Management review protocols, standards, and methodology by principals in the firm who possess a high degree of expertise that includes over twenty years of knowledge and experience in the development, implementation, and evaluation of corporate CPs.

Strategic Management submits this report with the understanding that many of the factors accepted and credited to BHS were predicated on representations by the organization’s management. The major finding was that the factors examined during the review track to the material points of concern expressed by the U.S. Sentencing Commission, DHHS OIG, and DOJ. The Review found evidence supporting that BHS is operating their Compliance Program consistent with these standards. The review findings, as qualified above, were sufficiently supported to draw those conclusions, and that the suggested courses of action to advance the Compliance Program effectiveness are reasonable and will meet the standards set forth in the cited authorities.

Independently reviewed and certified by:



Richard P. Kusserow, CEO

Date 05/06/2021