Sample Questions Governing Boards Can Ask Compliance Officers Privately or in Executive Session

- Do you have the resources (money, staff, tools) to fulfill your responsibilities?
- Do you have access to the people, information, and data that you need to fulfill your responsibilities?
- Do you have sufficient authority to complete your job?
- Do people listen to you when you speak? Do they take your concerns seriously?
- Are you or your staff regularly included in meetings where new strategies, projects, directions, or initiatives are discussed so that you can provide input from the beginning on possible risks and ways to achieve the goal compliantly?
- What are the top three things you are working on now?
- What are the top three risks that you are monitoring?
- What is your greatest concern?

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

IN RE THE BOEING COMPANY DERIVATIVE LITIGATION	))	C.A. No. 2019-0907-MTZ

MEMORANDUM OPINION

Date Submitted: June 25, 2021
Date Decided: September 7, 2021

Joel Friedlander, Jeffrey M. Gorris, and Christopher M. Foulds, FRIEDLANDER & GORRIS, P.A., Wilmington, Delaware; Richard M. Heimann and Katherine Lubin Benson, LIEFF CABRASER HEIMANN & BERNSTEIN, LLP, San Francisco, California; Steven E. Fineman, Nicholas Diamond, Sean Petterson, Rhea Ghosh, and Kartik S. Madiraju, LIEFF CABRASER HEIMANN & BERNSTEIN, LLP, New York, New York, *Attorneys for Co-Lead Plaintiffs*.

Blake Rohrbacher, Kevin M. Gallagher, and Ryan D. Konstanzer, RICHARDS, LAYTON & FINGER, P.A., Wilmington, Delaware; Joshua Z. Rabinovitz, KIRKLAND & ELLIS LLP, Chicago, Illinois, *Attorneys for Defendants and Nominal Defendant The Boeing Company*.

ZURN, Vice Chancellor.

A 737 MAX airplane manufactured by The Boeing Company ("Boeing" or the "Company") crashed in October 2018, killing everyone onboard; a second one crashed in March 2019, to the same result. Those tragedies have led to numerous investigations and proceedings in multiple regulatory and judicial arenas to find out what went wrong and who is responsible. Those investigations have revealed that the 737 MAX tended to pitch up due to its engine placement; that a new software program designed to adjust the plane downward depended on a single faulty sensor and therefore activated too readily; and that the software program was insufficiently explained to pilots and regulators. In both crashes, the software directed the plane down.

The primary victims of the crashes are, of course, the deceased, their families, and their loved ones. While it may seem callous in the face of their losses, corporate law recognizes another set of victims: Boeing as an enterprise, and its stockholders. The crashes caused the Company and its investors to lose billions of dollars in value. Stockholders have come to this Court claiming Boeing's directors and officers failed them in overseeing mission-critical airplane safety to protect enterprise and stockholder value.

Because the crashes' second wave of harm affected Boeing as a company, the claim against its leadership belongs to the Company. In order for the stockholders to pursue the claim, they must plead with particularity that the board cannot be

entrusted with the claim because a majority of the directors may be liable for oversight failures. This is extremely difficult to do. The defendants have moved to dismiss this action, arguing the stockholders have failed to clear this high hurdle.

The narrow question before this Court today is whether Boeing's stockholders have alleged that a majority of the Company's directors face a substantial likelihood of liability for Boeing's losses. This may be based on the directors' complete failure to establish a reporting system for airplane safety, or on their turning a blind eye to a red flag representing airplane safety problems. I conclude the stockholders have pled both sources of board liability. The stockholders may pursue the Company's oversight claim against the board. But the stockholders have failed to allege the board is incapable of maintaining a claim against Boeing's officers. The stockholders' other claim against the board, regarding their handling of the chief executive officer's retirement and compensation, is also dismissed.

I. BACKGROUND

I draw the following facts from the Verified Amended Consolidated Complaint, as well as the documents attached and integral to it.[1]

[1] Docket Item ("D.I.") 131 [hereinafter "Am. Compl]. *See, e.g.*, *Himawan v. Cephalon, Inc.*, 2018 WL 6822708, at *2 (Del. Ch. Dec. 28, 2018); *In re Gardner Denver, Inc. S'holders Litig.*, 2014 WL 715705, at *2 (Del. Ch. Feb. 21, 2014). Citations in the form of "Defs.' Ex. —" refer to the exhibits in support of Defendants' Motion, available at D.I. 147 through D.I. 152 and D.I. 160. Citations in the form of "Pls.' Ex. —" refer to exhibits in support of Plaintiffs' opposition to the Motion, available at D.I. 155. And citations in

Co-Lead Plaintiffs are Boeing stockholders. Co-Lead Plaintiff Thomas P. DiNapoli is Comptroller of the State of New York, Administrative Head of the New York State and Local Retirement System, and Trustee of the New York State

---

the form of "Hr'g Tr. —" refer to the transcript of the June 25, 2021 oral argument on Defendants' Motion, available at D.I. 169.

Prior to filing this action, Plaintiffs pursued and received books and records pursuant to 8 *Del. C.* § 220. Plaintiffs received over 44,100 documents totaling over 630,000 pages. It is reasonable to infer that exculpatory information not reflected in the document production does not exist. *See Teamsters Local 443 Health Servs. & Ins. Plan v. Chou*, 2020 WL 5028065, at *24 & n.314 (Del. Ch. Aug. 24, 2020).

The Amended Complaint cites documents Plaintiffs obtained under Section 220. The parties do not contest that under the incorporation by reference doctrine, I may consider those documents and Defendants' exhibits in support of the Motion to determine whether the Amended Complaint has accurately referenced their contents in support of its claims and in pleading demand futility. *Reiter on Behalf of Cap. One Fin. Corp. v. Fairbank*, 2016 WL 6081823, at *5–6 (Del. Ch. Oct. 18, 2016).

In briefing, Plaintiffs did not assert that any of the exhibits Defendants submitted would be improper to consider on the Motion. *See* D.I. 155 at 1 n.1 & 42–44. At argument, Plaintiffs' counsel suggested that the Court should not consider Dennis Muilenburg's "Lion Air Talking Points" for the Board's November 23, 2018 call, submitted as Defendants' Exhibit 86. *See* Hr'g Tr. 125–27. Specifically, Plaintiffs' counsel argued that "it is on its face a draft set of talking points that Mr. Muilenburg had"; and that "it's not incorporated by reference" because Plaintiffs "didn't plead that they were recited . . . to the board," "it's not a board meeting," and "[i]t's not a presentation," but "could have been." *Id.* 125. But Plaintiffs pled that "[t]alking points for the call circulated among Muilenburg and other executives expressed skepticism about media accounts of MCAS's role in the crash." Am. Compl. ¶ 224. Plaintiffs' brief in opposition to the Motion also relied on the talking points. *See* D.I. 155 at 26. Defendants submitted Exhibit 86 in reply. *See* Defs.' Ex. 86. I therefore consider Defendants' Exhibit 86 on the Motion.

At Defendants' urging, I have considered their proffered exhibits to determine if they show that Plaintiffs "misrepresented their contents" or if any inference that Plaintiffs seek is unreasonable. *Flannery v. Genomic Health, Inc.*, 2021 WL 3615540, at *8 (Del. Ch. Aug. 16, 2021) (citing *Voigt v. Metcalf*, 2020 WL 614999, at *9 (Del. Ch. Feb. 10, 2020)). Through that lens, I find they do no such work for Defendants; in fact, Defendants' exhibits support Plaintiffs' allegations.

Common Retirement Fund ("NYSCRF"). NYSCRF is a public pension fund for New York State and local government employees. Co-Lead Plaintiff Fire and Police Pension Association of Colorado ("FPPA") is the Trustee for the Fire and Police Members' Benefit Investment Fund, which contains assets of governmental defined benefit pension plans for Colorado firefighters, police officers, and their beneficiaries. As of June 8, 2020, FPPA held approximately 9,165 shares of Boeing stock, and NYSCRF held approximately 1,186,627 shares of Boeing stock.

Nominal Defendant Boeing is a global aerospace corporation that designs, manufactures, and sells commercial airplanes and other aviation equipment for the airline, aerospace, and defense industries. Boeing conducts its business in four segments. Its Boeing Commercial Airplanes ("BCA" or "Commercial Airplanes") segment is by far the most lucrative, generating approximately 61.7% of the Company's revenue in 2017 and 45% of its revenue in 2019. That decrease resulted from two fatal crashes involving Boeing's 737 MAX airplanes in 2018 (the "Lion Air Crash") and 2019 (the "Ethiopian Airlines Crash"). Those tragedies caused preventable loss of life, as well as the grounding of Boeing's entire 737 MAX fleet in March 2019 (the "737 MAX Grounding") and attendant financial and reputational harm to the Company. Plaintiffs seek to hold the defendants in this action

accountable for those harms under the principles articulated in *In re Caremark International Inc. Derivative Litigation*[2] and *Marchand v. Barnhill*.[3]

The defendants are current and former Boeing officers (the "Officer Defendants") and members of Boing's Board of Directors (the "Board") (the "Director Defendants," and together with the Officer Defendants, "Defendants"), who allegedly failed to oversee and monitor airplane safety. The Director Defendants include Dennis A. Muilenburg, W. James McNerney Jr., Kenneth M. Duberstein, David L. Calhoun, Mike S. Zafirovski, Admiral Edmund P. Giambastiani Jr., Susan C. Schwab, Caroline B. Kennedy, Arthur D. Collins Jr., Edward M. Liddy, Ronald A. Williams, Lynn J. Good, Randall L. Stephenson, Robert A. Bradway, and Lawrence W. Kellner.[4]

Many of Boeing's Board seats were long-term and awarded to political insiders or executives with financial expertise. For example, Duberstein, the longest-tenured Defendant and a lobbyist with "ultimate insider status," served as a McDonnell Douglas director from 1989 to 1997, and then as a Boeing director from 1997 through April 2019, including as Lead Director from 2005 through April 2018.[5]

---

[2] 698 A.2d 959 (Del. Ch. 1996).

[3] 212 A.3d 805 (Del. 2019).

[4] Plaintiffs allege Defendant Raymond L. Conner was "vice chairman of Boeing" from 2014 to 2017. Am. Compl. ¶ 39. It is unclear whether Conner was vice chairman of the Board. If he was a director, he is included as a "Director Defendant."

[5] Am. Compl. ¶ 23.

Duberstein was succeeded in that role by Defendant David L. Calhoun, a private equity executive, who has been a Boeing director since 2009; was appointed Board Chairman in October 2019 in the wake of the 737 MAX crashes; and was appointed Boeing's President and CEO in January 2020.

The Officer Defendants have also had extensive tenures at Boeing. They include the following:

- McNerney has been with Boeing since at least 2001. He served as Boeing's CEO, President, and Chairman of the Board from 2005 until February 2016.
- Muilenburg is a career Boeing executive who started with the Company in 1985. He became Boeing's Vice Chairman, President, and COO in December 2013; CEO in July 2015; and CEO and Chairman of the Board in March 2016, succeeding McNerney. After the 737 MAX crashes, in October 2019, Muilenburg was removed as Chairman and ultimately retired from the Company in December 2019.
- Defendant J. Michael Luttig served as Boeing's EVP and General Counsel from May 2006 to May 2019. In May 2019, following the grounding of the 737 MAX, Luttig was named Counselor and Senior Advisor to CEO Muilenburg and the Board, but left the Company in December 2019.

- Defendant Raymond L. Conner joined Boeing in 1977. He served as Boeing's Vice Chairman from 2014 until his retirement in 2017, and President and CEO of BCA from 2014 until November 2016.
- Defendant Kevin G. McAllister was Boeing's Executive Vice President and President and CEO of BCA from November 2016 (succeeding Conner) until his ouster in October 2019, following the Ethiopian Airlines Crash.
- Defendant Greg Hyslop has been Boeing's chief engineer since July 2016, overseeing all aspects of safety and technical integrity of Boeing products and services. Hyslop is also a member of Boeing's Executive Council and reports to the Company's President and CEO.
- Defendant Diana L. Sands is a member of Boeing's Executive Council and has served as Senior Vice President of Boeing's Office of Internal Governance and Administration since April 2014. As Boeing's chief ethics and compliance officer, she leads Boeing's ethics, compliance, corporate audit and trade controls activities, and reports to Boeing's President and CEO and to Boeing's Audit Committee, discussed *infra*.
- Defendant Greg Smith has served as Boeing's CFO since 2011.

In these roles, Defendants allegedly failed to carry out their respective duties to monitor the safety and airworthiness of Boeing's aircraft, and the extent of those

alleged failures only surfaced in the wake of corporate trauma. Rather than prioritizing safety, Defendants lent their oversight authority to Boeing's agenda of rapid production and profit maximization. That misplaced Board focus caused Boeing to bleed millions of dollars in fees, fines, and lost revenue, yet the Company rewarded several of the Defendants with hefty compensation and retirement packages.

A. Boeing Shifts Its Focus From Engineering And Safety To Profits And Rapid Production.

Founded in 1916, Boeing thrived as "an association of engineers."[6] Its executives were "conversant in engineering requirements."[7] As a result, Boeing's culture emphasized engineering and safety, and Boeing emerged as a leading global aerospace manufacturer.

As the Company grew, its focus on safety and engineering fell away. In 1997, Boeing acquired McDonnell Douglas, another airplane manufacturer with a long history of pushing profits, shirking quality control, and designing products involved in numerous safety incidents. With former McDonnell Douglas leaders at the helm, Boeing's corporate culture shifted from "safety to profits-first" and "focusing on

[6] Am. Compl. ¶ 44.

[7] *Id.*

costs-cutting rather than designing airplanes."[8] As observed by a longtime Boeing physicist:

> If your business model emphasizes productivity, employee engagement, and process improvement, costs go down faster. This was the essence of the "quality" business model Boeing followed in the mid-90s.
>
> The 777 had the best "learning curve" in the business. On the other hand, if your industry is mature, and your products are commodity-like, business school theory says a cost-cutting model is appropriate.
>
> Wal-Mart perfected its particular version of the cost-cutting business model. Amazon adapted that model to its industry. Boeing has adapted it to high-end manufacturing.[9]

As a result, many of Boeing's engineers felt disenchanted, and in 2000 they staged a forty-day strike to improve Company culture and regain a voice in decision making. By 2001, Boeing relocated its headquarters from Seattle to Chicago in order "to escape the influence of the resident flight engineers."[10]

The internal shift to focus on cost-cutting exacerbated the inherent risks associated with Boeing's business. In the early 2000s, Boeing saw a sharp rise in safety violations imposed by the Federal Aviation Administration (the "FAA").

---

[8] *Id.* ¶ 47.

[9] *Id.* ¶ 55 (quoting Stan Sorscher, a longtime Boeing physicist and negotiator for the Society for Professional Engineering Employees in Aerospace).

[10] *Id.* ¶ 5; *see also id.* ¶ 50. As Boeing's then-CEO Phil Condit explained, "When the headquarters is located in proximity to a principal business—as ours was in Seattle—the corporate center is inevitably drawn into day-to-day business operations." *Id.*

Between 2000 and 2020, the FAA flagged twenty airplane safety violations for poor quality control, poor maintenance, and noncompliant parts, as well as the Company's failure to provide its airline clients with crucial safety information.[11] Consequently, Boeing faced fines ranging between $6,000 and $13 million.

Quality suffered, and the Company was widely criticized, with prosecutors asking, "Where was the leadership?"[12] Management scandals ultimately led to the ouster of two successive CEOs. Then, in 2005, McNerney was named CEO. McNerney did not have a technical background, and after his appointment, Boeing was described as a "weird combination of a distant building with a few hundred people in it and a non-engineer with no technical skills whatsoever at the helm."[13]

The Company's safety record in the years that followed was spotty. In 2013, the new 787 Dreamliner suffered a series of lithium-ion battery fires and was grounded by the FAA. In 2014, the National Transportation Safety Board ("NTSB") directed Boeing to modify its process for developing safety assessments for designs incorporating new technology, after having determined that (1) Boeing had made misleading and unfounded claims about the lithium-ion battery system in its safety assessment reports to the FAA; (2) Boeing's certification engineers had not properly

---

[11] *See id.* ¶ 49. In comparison, the FAA cited Boeing's competitor, Airbus, for only three safety violations during the same period. *Id.*

[12] *Id.* ¶ 52.

[13] *Id.* ¶ 53.

tested the lithium-ion battery system; and (3) Boeing's safety assessment was insufficient. *Al Jazeera* also conducted and released an investigative report that detailed employee reports of ineffective quality control at a Dreamliner plant that resulted in "foreign object debris" being left in the aircraft, and disclosed that a Boeing customer was refusing to accept Dreamliners manufactured in that plant due to quality concerns.[14]

In addition to the Dreamliner issues, in July 2013, one of Boeing's 777 airplanes crashed, killing three and seriously injuring dozens. An NTSB report concluded that the crash was caused, at least in part, by inadequate plane documentation and training manuals, and recommended improvements in those areas.

Boeing's safety woes continued into 2015 as reflected in thirteen separate pending or potential civil enforcement cases relating to quality control, safety protocol violations, and manufacturing errors in production lines. The FAA investigated these claims and Boeing's failure to take appropriate corrective actions. In December 2015, Boeing entered into an unprecedented settlement with the FAA (the "FAA Settlement") and agreed to pay historic fines of $12 million, with up to $24 million in additional fines deferred pending Boeing acting on a five-year implementation of "additional significant systemic initiatives, to strengthen its

[14] *Id.* ¶¶ 118–21.

regulatory compliance processes and practices."[15] On February 25, 2021, the FAA announced in a press release it had assessed an additional $6.6 million in deferred civil penalties and settlement costs against Boeing.[16]

B. Boeing Lacked Any Formal, Board-Level Process To Oversee Airplane Safety.

Boeing did not implement or prioritize safety oversight at the highest level of the corporate pyramid. None of Boeing's Board committees were specifically tasked with overseeing airplane safety, and every committee charter was silent as to airplane safety. The Board recognized as much: former director John H. Briggs, who retired in 2011, observed that the "board doesn't have any tools to oversee" safety.[17] This stood in contrast to many other companies in the aviation space whose business relies on the safety and flightworthiness of airplanes.[18]

From 2011 until August 2019, the Board had five standing Committees to monitor and oversee specific aspects of the Company's business: (1) Audit, (2) Finance, (3) Compensation, (4) Special Programs, and (5) Governance, Organization and Nominating. The Audit Committee was Boeing's primary arbiter for risk and compliance. Specifically, it "evaluat[ed] overall risk assessment and

---

[15] *Id.* ¶ 123.

[16] Pls.' Ex 1.

[17] Am. Compl. ¶ 57.

[18] *Id.* ¶ 67 (identifying board-level safety committees and control at Southwest Airlines, Delta Airlines, United Airlines, JetBlue, Spirit Airlines, and Alaska Airlines).

risk management practices"; "perform[ed a] central oversight role with respect to financial statement, disclosure, and compliance risks"; and "receiv[ed] regular reports from [Boeing's] Senior Vice President, Office of Internal Governance and Administration with respect to compliance with our ethics and risk management policies."[19]

The Audit Committee's charter identifies its responsibilities as

- "[o]btain[ing] and review[ing], on an annual basis, a formal written report prepared by the independent auditor describing [Boeing's] internal quality-control procedures";
- reviewing "[a]ny material issues raised by the most recent internal quality-control review, or peer review, of [Boeing], or by any inquiry or investigation by governmental or professional authorities, within the preceding five years, respecting one or more independent audits carried out by [Boeing]";
- "[d]iscuss[ing] with management the Company's policies, practices and guidelines with respect to risk assessment and risk management";
- "[a]t least annually receiv[ing] reporting by the [Senior Vice President, Office of Internal Governance and Administration] on the Company's

[19] *Id.* ¶ 59.

compliance with its risk management processes, and by the General Counsel on pending Law Department investigations of alleged or potentially significant violations of laws, regulations, or Company policies"; and

- "[m]eet[ing] with the [Senior Vice President, Office of Internal Governance and Administration] to review the Company's ethics and business conduct programs and the Company's compliance with related laws and regulations."[20]

The Audit Committee was obligated to regularly report to the Board regarding those topics, including "the Company's compliance with legal or regulatory requirements," and "the implementation and effectiveness of the Company's ethics and compliance programs to support the Board's oversight responsibility."[21]

Although the Audit Committee was tasked with handling risk generally, it did not take on airplane safety specifically. Its yearly updates regarding the Company's compliance risk management process did not address airplane safety. For example, when the Board discussed audit plans in 2014 and 2017, respectively, it did not mention or address airplane safety. Specifically as to the 737 MAX, from its development through its grounding in 2019, the Audit Committee never mentioned

[20] *Id.* ¶ 61.

[21] *Id.* ¶ 62.

"safety."[22] Nor did it address product safety issues related to the design, development, or production of the 737 MAX, or ask for presentations on the topic.

Rather, consistent with Boeing's emphasis on rapid production and revenue, the Audit Committee primarily focused on financial risks to the Company. For example, its February 2011 audit plan focused on "production rate readiness activities" and "supplier management rate readiness."[23] Its presentations centered on whether Boeing had liquidity, capital, and supply chain resources sufficient to fund aggressive production of the 737 MAX.[24] Even after the Lion Air Crash in 2018, chief compliance officer Sands's risk management update to the Audit Committee in December 2018 did not identify product safety as a "compliance risk" for 2018.[25]

The Audit Committee also oversaw an Enterprise Risk Visibility ("ERV") process.[26] The ERV process annually provided senior management and the Board with a "comprehensive view of key Boeing Risks and the actions taken to address them," as curated from "[a]ll business units, major functions, and risk and

---

[22] *Id.* ¶¶ 60, 62–64.

[23] *Id.* ¶ 64.

[24] *See* Defs.' Ex. 6; Defs.' Ex. 10; Am. Compl. ¶¶ 60, 63; *see also infra* note 32.

[25] Am. Compl. ¶ 65.

[26] Defs.' Ex. 7 at -14500; Hr'g Tr. 9.

compliance disciplines."[27] The Audit Committee annually reviewed the top strategic, operational, and compliance risks the ERV process identified, and subsequently reported those risks to the Board, which in turn reviewed management's mitigation of those risks.[28] The ERV process also played an important role in Boeing's internal Corporate Audit group, which evaluated priority risk areas within the Company.[29] Based on the results of annual ERV risk assessments, the Corporate Audit group annually submitted an audit plan to review top risks.[30] But neither the Corporate Audit group nor the ERV process specifically emphasized airplane safety; they primarily focused on production and financial risks.[31]

Airplane safety was not a regular set agenda item or topic at Board meetings. Audit Committee and ERV materials reveal that airplane safety risks were not discussed.[32] While the Board sometimes discussed production line safety, the Board

---

[27] Defs.' Ex. 7 at -14501.

[28] *Id*. at -14502–04.

[29] Defs.' Ex. 9 at -14488; Defs.' Ex. 10 at -17591; Hr'g Tr. 9.

[30] Defs.' Ex. 9 at -14488–89.

[31] *See* Defs.' Ex. 7; Defs.' Ex. 8 at -11183–84; Defs.' Ex. 9; Defs.' Ex. 10 at -17575–92; Defs.' Ex. 23; Defs.' Ex. 24 at -16424, -16426; Defs.' Ex. 25 at -16997; *see also infra* note 32.

[32] Defs.' Ex. 6; Defs.' Ex. 7 at -14501–04; Defs.' Ex. 9 at -14489–90, -14495; Defs.' Ex. 10; Defs.' Ex. 13; Defs.' Ex. 23; Defs.' Ex. 24 at -16424, -16426; Defs.' Ex. 25 at -16981; *see also* Am. Compl. ¶¶ 64–66. Discussions or mentions of "safety" are similarly absent from the Audit Committee Report and Enterprise Risk Visibility Review sections of the Board meeting minutes Defendants submitted. Ex. 8 at -11183–84, -11187; Defs.' Ex. 11

often met without mentioning or discussing safety at all.[33] The Board did hear presentations discussing "Environment, Health & Safety,"[34] including regarding the workplace safety program "Go4Zero."[35] Communications mentioning "safety," "quality," or "risk" do not reflect substantive discussion related to airplane safety.[36]

---

at -12506; Defs.' Ex. 12 at -12648–49; Defs.' Ex. 19 at -11606; Defs.' Ex. 26 at -13570, -13573; Defs.' Ex. 27 at -11921–23; Defs.' Ex. 28; Defs.' Ex. 29; Defs.' Ex. 34 at -12382–83; Defs.' Ex. 37 at -12972; Defs.' Ex. 39 at -8135; Defs.' Ex. 44; *see also* Am. Compl. ¶ 64. Defendants' Exhibits 28, 29, 39, and 44 were largely redacted in Defendants' Section 220 production.

[33] Defs.' Ex. 11; Defs.' Ex. 12; Defs.' Ex. 18; Defs.' Ex. 37; Defs.' Ex. 38; Defs.' Ex. 40; Defs.' Ex. 42; Defs.' Ex. 43; Defs.' Ex. 44; Defs.' Ex. 46; Defs.' Ex. 50; Defs.' Ex. 51; Defs.' Ex. 52. These documents do not support Defendants' argument that the Board had a reporting structure and processes to oversee airplane safety and the 737 MAX. *See* Hr'g Tr. 8.

[34] *See, e.g.*, Defs.' Ex. 9 at -14495 (listing "safety" within "Environment, Health & Safety" in the Appendix D Risk Universe); Defs.' Ex. 10 at -17589 ("Supply Chain Operations (SCO) Environment, Health & Safety, Safety Management System Renton 737 Programs Governance" and "Evaluate processes for Renton site safety oversight related to 'Go for Zero' execution to achieve overall relevant Enterprise Safety objectives"); *see also* Defs.' Ex. 7; Defs.' Ex. 10 at -17572–73, -17583, -17587; Defs.' Ex. 20 at -13047, -13066; Defs.' Ex. 23 at -15866; Defs.' Ex. 24 at -16426; Defs.' Ex. 25 at -16981; Defs.' Ex. 84 at -618225, -618235, -618240, -618242, -618248.

[35] *See, e.g.*, Defs.' Ex. 19 at -11603 ("Mr. Shanahan then provided a Safety Update. He began by reviewing the evolution of the 'Go for Zero' safety program since 2007. He next reviewed safety performance and workplace injury statistics for operations and non-operations activities. Mr. Shanahan then reviewed safety focus areas, including improvements in final assembly and structures manufacturing, ongoing prevention activities and the roles of data analytics in improving safety performance."); *see also* Defs.' Ex. 10 at -17589; Defs.' Ex. 16 at -11076; -11078; Defs.' Ex. 17 at -11646.

[36] Defs.' Ex. 6 at -20519; Defs.; Ex. 8 at -11183; Defs.' Ex. 16 at -11073, -11077–80; Defs.' Ex. 17 at -11646; Defs.' Ex. 20 at -13057; Defs.' Ex. 21 at -2692; Defs.' Ex. 22 at -18837–38 ("Model-Based Engineering (MBE) – Progress . . . Improve safety, quality, productivity, cost"); Defs.' Ex. 25 at -16997; Defs.' Ex. 37 at -12967; Defs.' Ex. 39 at -8133, -8135; Defs.' Ex. 40 at -8086; Defs.' Ex. 41 at -8315; Defs.' Ex. 42 at -12481; Defs.' Ex. 43 at -12842; Defs.' Ex. 44 at -2501; Defs.' Ex. 45 at -1960; Defs.' Ex. 50 at -2711;

Management's periodic reports to the Board did not include safety information. Muilenburg sent the Board a monthly business summary and competitor dashboard, and management made occasional presentations at Board meetings.[37] Those management communications focused primarily on the business impact of airplane safety crises and risks.[38]

Further, the Board did not have a means of receiving internal complaints about airplane safety. Before 2019, Boeing's principal internal safety reporting process was the Safety Review Board ("SRB"). The SRB was Boeing's principal internal safety reporting process, but it had no link to the Board and no Board reporting mechanism.[39] The SRB operated below the level of the most senior officers; the complaints and concerns fielded by the SRB were handled by Boeing's mid-level management like the Program Functional Chief Design Engineer, the Chief Pilot, the Chief Project Engineer, and the Product Safety Chief Engineer and factory leaders. Without a Board-level reporting mechanism, safety issues and whistleblower complaints reported to the SRB did not come to the Board's attention.

Defs.' Ex. 52 at -11401; Defs.' Ex. 62 at -13680–81; Defs.' Ex. 63 at -13682; Defs.' Ex. 70 at -13684.

[37] *See, e.g.*, Defs.' Ex. 62.

[38] Am. Compl. ¶¶ 7, 8, 14, 17, 18, 57–76; *see* Defs.' Ex. 60 at -13677; Defs.' Ex. 73 at -2944; Defs.' Ex. 74 at -2947; *see also supra* notes 34-36 and accompanying text.

[39] Hr'g Tr. 30–33; Am. Compl. ¶¶ 74–76.

Neither the Audit Committee, nor any other Board committee, reviewed whistleblower complaints related to product safety.

C. Boeing Develops The 737 MAX In An Effort To Outpace Its Competitors.

With the Board so distanced from safety information, and on the heels of recent safety incidents and inquiries, Boeing continued to push production and forego implementing meaningful systems to monitor airplane safety. Boeing's primary production focus was on its "blockbuster" 737 MAX, which became one of the Company's key revenue sources.[40]

By 2008, Boeing was falling behind on production and sales as compared to its primary competitor, Airbus. In 2010, Airbus announced its fuel-efficient A320neo, which sold well and quickly gained ground on Boeing's 737, which had not been updated since the late 1990s. As Boeing clients began considering Airbus's fuel-efficient jets, Boeing felt production and sales pressure.

In 2010 and early 2011, Boeing considered two options for updating its existing 737 Next Generation ("737 NG") model: either develop an entirely new airplane, which could take a decade, or redesign the current model with larger, more efficient engines in six years. In an effort to regain competitive ground, and amid concerns about production cost and timing, Boeing elected to update the 737 NG. If

[40] *See* Am. Compl. ¶ 6.

developed as a "derivative plane," Boeing would only need to secure FAA certification for those changes between the 737 NG and the new plane.[41] The FAA assesses the minimum level of "differences training" required for a pilot to fly a new airplane by evaluating the similarity between the new and prior versions of the airplane.[42]

At a June 2011 Board meeting, the Board and senior management considered the potential redesign of the 737 NG. Jim Albaugh, Head of BCA, pressed the production and sales benefits of the 737 NG's potential "re-engine": gains in fuel efficiency, non-recurring investment costs, capital costs, and expedited re-design schedules.[43] The Board concluded the reconfigured airplane would have larger and more fuel-efficient engines intended to "restore[] competitive advantage over [Airbus's] NEO."[44]

So at an August 2011 Board meeting, the Board approved development of Boeing's next generation of narrow-body commercial aircraft: the 737 MAX, which would be a reconfigured version of the 737 NG that "incorporat[ed] new engine technology and such other modifications and upgrades as are deemed appropriate in

---

[41] *Id.* ¶ 138.

[42] *Id.* ¶ 163.

[43] *Id.* ¶ 133.

[44] *Id.*

light of prevailing market conditions."[45] The August 2011 Board minutes describe the "strategy and objectives associated with a re-designed 737 airplane, including increasing customer value, maintaining market share and a competitive advantage over the Airbus 320neo, reducing risk and enabling wide body product investment."[46] According to three people present at the August Board meeting, no Board member asked about the safety implications of reconfiguring the 737 NG with larger engines. Rather, the Board inquired about engine options, program personnel, development schedule contingencies, and customer contract provisions regarding performance and penalties; the Board's primary concern was "how quickly and inexpensively the Company could develop the 737 MAX model to compete with Airbus's A320neo."[47] The Board delegated to McNerney all authority over the multi-year effort to approve the 737 MAX's final specifications, and deliver and build it, without having to return to the Board.

1. Boeing Implements The "MCAS" System In The 737 MAX.

In developing and marketing the 737 MAX, Boeing prioritized (1) expediting regulatory approval and (2) limiting expensive pilot training required to fly the new model. As explained by a former Boeing engineer who worked on the 737 MAX's

[45] *Id.* ¶ 135; *see id.* ¶¶ 6, 133–34.

[46] *Id.* ¶ 267.

[47] *Id.* ¶ 134.

flight controls, Boeing "wanted to A, save money and B, to minimize the certification and flight-test costs."[48]

Because the Company was months behind Airbus in developing a new airplane, Boeing set a "frenetic" pace for the 737 MAX program, resulting in hastily delivered technical drawings and sloppy, deficient blueprints.[49] Boeing's engineers were instructed to maintain "commonality" with the 737 NG in order to expedite FAA certification.[50] But maintaining commonality posed unique design issues.

In particular, the 737 MAX's larger engine needed to be situated differently on the airplane's wings, shifting its center of gravity. Because of that engine placement, the 737 MAX tended to tilt too far upwards, or "pitch up," in flight.[51] Initial attempts to resolve the issue with aerodynamic solutions failed. So Boeing addressed the issue with new software: the Maneuvering Characteristics Augmentation System, or "MCAS."[52] MCAS moved the leading edge of the plane's entire horizontal tail, known as the "horizontal stabilizer," to push the airplane's tail up and its nose down.[53]

---

[48] *Id.* ¶ 138.

[49] *Id.* ¶ 137.

[50] *Id.* ¶ 138 (explaining that "commonality" is "an industry term that evaluates how similar one model is to its predecessor").

[51] *Id.* ¶ 150.

[52] *Id.* ¶¶ 9, 152–53, 155.

[53] *Id.* ¶ 152.

As originally designed, MCAS would activate only if the plane pitched up at both a high angle of attack (or "AOA") and a high G-force (the plane's acceleration in a vertical direction). During 2016 flight testing, Boeing changed MCAS to allow it to activate at low speeds; as such, it "could be automatically triggered simply by a high AOA."[54]

The external sensor for AOA was highly vulnerable to false readings or failure for numerous reasons, such as general weather, lightning, freezing temperatures, software malfunctions, or birds. The AOA's sensor's vulnerability was well-known: between 2004 and 2019, failed AOA sensors were flagged to the FAA in more than 216 incident reports, including instances that required emergency landings. MCAS had only one AOA sensor, creating a "single point of failure" that violated the fundamental engineering principle requiring redundancy "so that one single error in a complex system does not cause total system failure."[55] If the single AOA sensor was triggered, even for a flawed reason unrelated to the plane's pitch, MCAS would "correct" the aircraft by pushing its nose down.[56]

---

[54] *Id.* ¶ 155.

[55] *Id.* ¶¶ 159–60. A 2011 FAA Advisory Circular warned that "[h]azards identified and found to result from probable failures are not acceptable in multiengine airplanes," and that "[i]n these situations, a design change may be required . . . such as increasing redundancy." *Id.* ¶ 159.

[56] *Id.* ¶ 190 ("[A]n analysis performed by the manufacturer showing that if an erroneously high single [AOA] sensor input is received by the flight control system, there is a potential for repeated nose-down trim commands of the horizontal stabilizer.").

In 2013, Boeing engineers proposed that the 737 MAX implement a Dreamliner safety feature called "synthetic airspeed" to detect a false AOA signal.[57] Managers rejected that proposal due to additional cost and pilot training, and MCAS remained dependent on a single fickle AOA sensor. Engineers remained skeptical; in late 2015, one queried: "[a]re we vulnerable to single AOA sensor failures with the MCAS implementation or is there some checking that occurs?"[58]

Boeing's analyses and FAA disclosures about MCAS underestimated its lethality. In 2014, Boeing submitted a System Safety Assessment (an "Assessment") to the FAA calculating the effect of possible MCAS failures. The Assessment did not consider the possibility that MCAS could trigger repeatedly, effectively giving the software unlimited authority over the plane. Boeing concluded MCAS was not a "safety-critical system."[59] After MCAS was revised to rely on the single AOA sensor, internal safety analyses concluded that MCAS could cause "catastrophic" failures if it took a pilot more than ten seconds to identify and respond to the software's activation.[60] But the analyses assumed the pilot would react within four seconds, and so concluded that the likelihood of a "hazardous event" due to an

---

[57] *Id.* ¶ 161.

[58] *Id.* ¶ 160.

[59] *Id.* ¶ 154.

[60] *Id.* ¶ 156.

MCAS failure was nearly inconceivable.[61] It would later be revealed that Boeing's four-second reaction time assumption was a "gross underestimate."[62]

Boeing did not update the 2014 FAA Assessment for MCAS as revised. Boeing's technical pilots deceived the FAA by failing to disclose that MCAS as revised activated only upon the AOA sensor signal, regardless of speed, increasing the likelihood that MCAS would activate.

2. Boeing Pushes Expedited Certification And Rapid Production.

Based on purported commonality with the 737 NG, Boeing sought "Level B" pilot training for the 737 MAX, which can be done on a tablet computer without costly flight simulator training.[63] More extensive training would incur additional costs, defeat the economies from commonality with the 737 NG, and make the 737 MAX less competitive with the Airbus 320neo. Between 2014 and 2017, Boeing touted that flight simulator training would not be necessary on the 737 MAX.

Boeing and its well-connected leadership had significant sway over the FAA, and the FAA often permitted Boeing to self-regulate. Boeing put "tremendous

---

[61] *Id.*

[62] *Id.*

[63] *Id.* ¶ 164.

pressure" on its Chief Technical Pilot Mark Forkner to obtain Level B pilot training for the 737 MAX.[64]

In August 2016, the FAA issued a provisional report establishing Level B training for the 737 MAX. In November, after Boeing had revised MCAS, Forkner texted a colleague that MCAS was "running rampant" on a flight simulator when operating at a low speed and then texted: "so basically I lied to the regulators (unknowingly)."[65] Still, Forkner stressed to the FAA that it should not reference MCAS in its report because it was "outside the normal operating envelop[e]."[66]

In July 2017, the FAA published the final 737 MAX report providing for Level B differences training determination. Based on Boeing's failure to submit a new Assessment on the revised MCAS and misrepresentation of MCAS's safety risks, the FAA deleted all information about MCAS from the July 2017 report.[67] Forkner emailed a Boeing colleague bragging that his "jedi mind tricks" had worked on the FAA.[68]

---

[64] *Id.* ¶ 105.

[65] *Id.* ¶ 169; *see id.* Ex. A; *id.* Ex. B at A-10.

[66] *Id.* ¶ 170 ("[O]ne of the Program Directives we were given was to not create any differences . . . That is what we sold to the regulators who have already granted us the Level B differences determination. *To go back to them now, and tell them there is in fact a difference . . . would be a huge threat to that differences training determination.*").

[67] *Id.* ¶ 106; *id.* Ex. B.

[68] *Id.* ¶ 171.

As a result of the FAA's decision, the 737 MAX airplane manuals and pilot training materials for U.S.-based airlines lacked specific information about MCAS.[69] Specifically, no substantive description of MCAS appeared in Boeing's three documents for pilots flying new models: (1) the Flight Crew Operations Manual ("FCOM"), the primary pilot reference; (2) the Quick Reference Handbook, a shorter emergency manual for abnormal flight situations; and (3) the Flight Crew Training Manual, which provides general recommendations on flying maneuvers and techniques. After the Lion Air and Ethiopian Airlines Crashes, senior FAA officials testified before Congress that MCAS should have been explained in those manuals.

After securing Level B training, Boeing continued to conceal issues with the 737 MAX. The airplane was supposed to have an "AOA disagree alert" to identify malfunction in the airplane's AOA sensor and prevent it from triggering MCAS's "repeated nose-down trim commands of the horizontal stabilizer."[70] That alert was a standard feature of the 737 NG.[71] Boeing included the alert in the March 2017 "type certificate" submitted to the FAA, so the alert was required in all planes produced.[72] But in August 2017, Boeing learned the alert did not function due to a

---

[69] *Id.* ¶¶ 106, 173; *id.* Ex. B.

[70] *Id.* ¶¶ 175, 190.

[71] *Id.* ¶ 175.

[72] *Id.* ¶ 177.

software issue; to make it work, customers needed to purchase an optional "add-on" feature for $80,000 called an "AOA indicator display."[73] The AOA disagree alerts did not work in at least 80% of the 737 MAX planes Boeing delivered—including the Lion Air and Ethiopian Airlines planes that crashed. Boeing did not tell the FAA or its customers that the majority of its planes had inoperable AOA disagree alerts until after the Lion Air Crash in 2018. And even after the 2019 Ethiopian Airlines Crash, Boeing continued to insist that the AOA indicator display was not a "required" safety feature and that it was appropriate to offer it as an optional "add on."[74] Boeing decided to repair the AOA disagree alert via a software update that was not scheduled to roll out until 2020.

3. Boeing Successfully Markets The 737 MAX In Emerging Markets And Presses The Board's Business Objectives; Boeing's Employees Question The 737 MAX's Safety, But Those Concerns Never Reach The Board.

Four months after announcing the 737 MAX in 2011, Boeing had logged more than 1,000 orders and commitments for the airplane from airlines and leasing customers worldwide. By 2014, Boeing had over 2,700 737 MAX orders from fifty-seven customers. And by the end of 2016, Boeing had 4,300 orders from ninety-two

[73] *Id.* ¶ 176.

[74] *Id.* ¶ 180.

customers. The 737 MAX had become the fastest-selling airplane in Boeing's history.

Many of those sales originated from Boeing's target customers in emerging markets. Boeing pursued those customers in a cost-saving and revenue-enhancing strategy, knowing that in many countries with expanding fleets of low-cost airlines, the quality of pilot training was not consistently as high as in the United States. Those countries took their safety cues from the FAA. Although Lion Air and Garuda Indonesia Airlines both initially requested simulator training on their newly purchased 737 MAX airplanes, Boeing pressed that computer-based training was sufficient.[75] Boeing never required or provided simulator training. By December 2017, Boeing had sold numerous 737 MAX airplanes to airlines in Southeast Asia, including Lion Air.

Boeing began fulfilling customer orders in May 2017.[76] By 2018, Boeing's profits from the 737 MAX skyrocketed.[77] The BCA accounted for approximately 60% of the Company's record $101.1 billion in annual revenue and approximately

---

[75] *Id.* ¶ 143 (explaining that "rather than provide costly simulator training, Boeing employees emphasized that the 'FAA, [European regulators], Transport Canada, China, Malaysia, and Argentinia [*sic*] authorities have all accepted the [computer-based training] requirement'").

[76] *Id.* ¶ 144.

[77] *Id.* ¶ 146.

$8 billion, or 80%, of the Company's annual net earnings.[78] By the end of 2018, the value of Boeing's total backlog of orders—a measure of financial health for an airplane manufacturer—had risen to $490 billion, with the BCA accounting for $412 billion and nearly 5,900 jetliners, more than 4,000 of which were 737 MAX airplanes.

Boeing struggled to keep up with demand and customer expectations and to meet the Board's production and delivery target of fifty-seven airplanes per month. In July and August 2018, deliveries averaged approximately thirty-nine airplanes per month. Falling behind, Boeing employees worked in a "factory in chaos," facing intense pressure to maintain production schedules.[79]

As Boeing's 737 MAX's sales accelerated, its employees grew concerned about the airplane's safety. For example, in summer 2018, a longtime general manager and engineer at the 737 MAX plant in Renton, Washington, tried to raise "Recovery Operations & Safety Concerns" with the 737 program's general manager and factory leader, writing, "[R]ight now all my internal warning bells are going off. . . . And for the first time in my life, I'm sorry to say that I'm hesitant about putting my family on a Boeing airplane."[80] At a meeting, the engineer expressed

---

[78] *Id.*

[79] *Id.* ¶ 148.

[80] *Id.* ¶ 87.

that he had "seen larger operations shut down for far less safety issues . . . in the military and those organizations have national security responsibilities."[81] The manager responded, "The military isn't a profit making organization."[82] The engineer retired from Boeing soon thereafter. Before and after the Lion Air Crash, similar concerns came in from other employees regarding unrelenting and dangerous economic pressure from senior management to produce the 737 MAX rapidly and cheaply.[83]

---

[81] *Id.* ¶ 89.

[82] *Id.*

[83] *See id.* ¶ 90 ("Separately, in 2018, . . . a Boeing engineering manager working on the 737 MAX, expressed frustration to Director of Global Operations . . . that Boeing had selected 'the lowest cost supplier and sign[ed] up to impossible schedules,' which reflected unrelenting and dangerous economic pressure from senior management: [']*I don't know how to fix these things* . . . it's systemic. It's culture. It's the fact that we have a senior leadership team that understand very little about the business and yet are driving us to certain objectives. . . . *Sometimes you just have to let things fail big so that everyone can identify a problem* . . . maybe that's what needs to happen rather than just continuing to scrape by.[']"); *id.* ¶ 91 ("In July 2018, Boeing's Test and Evaluation department voiced concerns to 'Boeing Executive Leadership' regarding the 'considerable pressure' the 737 MAX program faced over production schedules. The department's letter identifies the 'ero[sion of] safety margins' due to the declining average experience among senior production pilots. [Boeing's] Employee Relations Director . . . forwarded the communication to defendant Hyslop, Boeing's chief engineer, but . . . mischaracterized the letter as seeking mainly compensation and additional benefits, without flagging the safety concerns of overworked employees."); *id.* ¶ 92 ("[I]n November 2018, after the Lion Air Crash, . . . a Quality Assurance Inspector and nearly 30-year Boeing veteran, recounted mistreatment 'for reporting serious quality problems,' explaining that '[n]o one should have to go through this when trying to do what is right – to assure the quality of our product.' He added, 'I have stood alone during these past months trying to assure that we have addressed these quality issues. I had only hoped that management would have stood with me.' [The employee] identified another whistleblower . . . a former quality specialist and compliance monitor, whom he said was also harassed in retaliation for reporting of 'quality concerns' related to the 737 MAX.").

While some of these complaints made their way to senior management, none made it to the Board. The Board was unaware of whistleblower complaints regarding airplane safety, compliance, workforce exhaustion, and production schedule pressure at the 737 MAX facility.

D. Undisclosed Issues With The 737 MAX Ultimately Cause The Lion Air and Ethiopian Airlines Crashes; The Board Continues To Shirk Safety Oversight, Receiving Only Sporadic Updates About The 737 MAX From Management.

On October 29, 2018, a new 737 MAX flying as Lion Air Flight 610 crashed in the Java Sea minutes after taking off from Jakarta, Indonesia, killing all 189 passengers and crew. Satellite data show the plane rising and falling repeatedly, as MCAS continually activated to force the airplane's nose downwards. The plane's black box data revealed that the pilots searched the Quick Reference Handbook's checklist for abnormal flight events, but it said nothing about MCAS, which was later identified as the cause of the tragedy. Within days of recovering the black box, Boeing started revising MCAS.

The FAA quickly conducted a risk assessment analysis and concluded what many at Boeing already knew: that there was an unacceptably high risk of catastrophic failure if MCAS was not changed, estimating that the then-existing fleet of Boeing 737 MAX planes would average one fatal crash stemming from MCAS every two to three years if the software was not corrected. Boeing then conducted its own risk assessment and reached a conclusion consistent with the FAA's. On

November 6, Boeing issued an Operations Manual Bulletin to the airlines (the "Manual Bulletin"), stating, "[i]n the event of erroneous AOA sensor data, the pitch trim system can trim the stabilizer nose down in increments lasting up to 10 seconds."[84] It did not name MCAS.

The next day, November 7, the FAA issued an Emergency Airworthiness Directive (the "Emergency Directive"), indicating that "an unsafe condition exists that requires immediate action by an owner/operator."[85] The Emergency Directive described "an analysis performed by the manufacturer showing that if an erroneously high single [AOA] sensor input is received by the flight control system, there is a potential for repeated nose-down trim commands of the horizontal stabilizer."[86] The FAA mandated that Boeing revise its flight manuals "to provide the flight crew horizontal stabilizer trim procedures to follow under certain conditions."[87] In response, Muilenburg emailed Greg Smith warning the mandate might harm productivity: "[w]e need to be careful that the [airplane flight manual] doesn't turn into a compliance item that restricts near-term deliveries."[88]

---

[84] *Id.* ¶ 188.

[85] *Id.* ¶ 189.

[86] *Id.* ¶ 190.

[87] *Id.* ¶ 191.

[88] *Id.* ¶ 211.

On November 12, *The Wall Street Journal* published an article entitled "Boeing Withheld Information on 737 Model, According to Safety Experts and Others" (the "*WSJ* Article").[89] It reported that "neither airline managers nor pilots had been told such a[n MCAS] system had been added to the latest 737 variant—and therefore aviators typically weren't prepared to cope with the possible risks."[90] It reported disdain by pilots who questioned why they were not properly trained on the MCAS system.[91] Finally, the *WSJ* Article reported that the FAA learned the new flight control systems "were not highlighted in any training materials or during lengthy discussions between carriers and regulators about phasing in the latest 737 derivatives" and that Boeing purposefully withheld that critical information.[92]

1. The Board Passively Receives Lion Air Crash Updates From Muilenburg, But Does Not Initiate Action.

Management did not bring the Lion Air Crash to the Board's attention for over a week. Muilenburg first contacted the Board, Smith, and McAllister regarding the Lion Air Crash on November 5.[93] His half-page email identified the players in the

---

[89] *Id.* ¶¶ 195–98; *id.* Ex. D.

[90] *id.* Ex D; *id.* ¶ 198.

[91] *Id.* Ex. D ("It's pretty asinine for them to put a system on an airplane and not tell pilots who are operating the airplane, especially when it deals with flight controls . . . . Why weren't they trained on it?"); *id.* ¶ 198.

[92] *id.* Ex. D; *id.* ¶ 197.

[93] *id.* ¶¶ 208–09; Defs.' Ex. 55.

investigation, reported that the Indonesian investigator "publicly said today that the airspeed indicator on the airplane that crashed was damaged during the last four flights of the airplane," and concluded, "We believe the 737 MAX fleet is safe."[94] It did not mention MCAS, the lack of redundancy for a faulty sensor, or the missing sensor alert or specific pilot instructions.

Muilenburg updated the Board again between November 8 and 23, spurred by unfavorable information about the 737 MAX and Lion Air Crash becoming public.[95] On November 13, Director Arthur Collins forwarded Muilenburg a news summary: "I am sure you have already read [the *WSJ* Article] and will brief the [B]oard on this topic."[96] Muilenburg consulted with then-current and former Lead Directors Calhoun and Duberstein about the *WSJ* Article and its fallout.[97] Calhoun advised Muilenburg to contact the Board. And so on November 13, Muilenburg sent a memo to the Board regarding the Lion Air Crash.[98] He told the Board the *WSJ* Article was "categorically false" and "wrongly claims Boeing withheld from customers and flight crews information related to a pitch augmentation system that's unique to the

[94] Defs.' Ex. 55.

[95] *See* Defs.' Ex. 53; Defs.' Ex. 56; Defs.' Ex. 57; Defs.' Ex. 58.

[96] Am. Compl. ¶ 212.

[97] *See id*. Ex. E.

[98] *See id*. Ex. D.

737 MAX."[99] And he blamed the Lion Air flight crew for the crash.[100] He did not explain that Boeing knew MCAS was vulnerable and susceptible to failure, nor that pilots were not informed about or trained on MCAS.

The next day, Muilenburg informed Duberstein that Calhoun "suggested that my note to the Board focus solely on the Lion Air matter given the importance and visibility," and that he would update the Board on Lion Air the following weekend.[101] Duberstein's response focused on the negative public reaction to the Lion Air Crash and its impact on production: "Press is terrible. Very tough. Lots of negative chatter I'm picking up. Not pleasant. We need to address more aggressively concerns merging re 737 line, deliveries, and Lion Air."[102] Muilenburg responded that he was "working all angles" on public relations, government relations, and investor relations, including "working airline operations leaders to get messages and counter pilot comments (who are motivated to get separate type rating for MAX – equals more pay)."[103]

On November 17, Boeing executives, including Muilenburg, Smith, McAllister, Hyslop, and Luttig, discussed a *Bloomberg* article that Muilenburg

---

[99] *Id.*; Defs.' Ex. 57.

[100] Am. Compl. Ex. D.

[101] *See id*. Ex. E.

[102] *Id.*

[103] *Id.*; *id*. ¶ 214.

characterized as "filled with misleading statements and inaccuracies – implying that we hid MCAS from operators and that procedures were not covered in training/manuals."[104]

On November 18, after *The New York Times* published an article addressing MCAS's role in the Lion Air crash, Muilenburg sent the Board another letter.[105] He bemoaned "a steady drumbeat of media coverage—and continued speculation—on what may have caused the accident" and again falsely suggested that the 737 MAX was safe.[106] Muilenburg took the same position in November 19 and 20 internal messages to Boeing employees and executives.

Then, on November 21, Muilenburg emailed the Board to invite them to an "optional" November 23 Board call for an update on the Lion Air Crash from Muilenburg, Luttig, and Smith.[107] This was the first time the Board convened after the crash. There are no minutes. Management's talking points for the call explained that erroneous AOA data "contributed to the mishap," and that the Lion Air repair shop may not have followed the approved repair process on the sensor.[108] The

---

[104] *Id*. ¶ 217.

[105] Defs.' Ex. 58; Am. Compl. ¶ 218.

[106] Defs.' Ex. 58.

[107] Am. Compl. ¶¶ 223–24; Defs.' Ex. 59 ("Consider this phone call 'optional', understanding that many of you have family and friend activities planned for this coming weekend.").

[108] Defs.' Ex. 86.

talking points included an explanation of MCAS, and described Boeing's post-Lion Air Crash updates to operators regarding erroneous AOA sensors and MCAS. They also explained the "further safety enhancement" of a software update "that will limit the airplane's response in case of erroneous AOA sensor data" and "further reduce the risk associated with a discrepant AOA sensor and help reduce pilot workload."[109] The talking points also provided that "the function performed by MCAS" was referenced in the FCOM, that the "appropriate flight crew response to uncommanded trim, regardless of cause, is contained in existing procedures," and that "any suggestion that we intentionally withheld information about airplane functionality from our customers simply isn't true."[110] They disclosed a meeting the week before with the acting FAA Administrator, who "understood how MCAS works and believes the 737 MAX is a safe airplane," and who knew about the repair shop investigation. Finally, the talking points expressed frustration with people "commenting freely, including customers, pilot unions, media, and aerospace industry punditry," and addressed Lion Air's orders, other customers' orders, and Boeing's stock price.[111]

---

[109] *Id.*

[110] *Id.*

[111] Am. Compl. ¶ 224; Defs.' Ex. 86.

Muilenburg's subsequent written communications to the Board again blamed Lion Air's crew, and stressed that Boeing's external statement denying its fault was "showing up in the initial media coverage, which has focused largely on Lion Air's operations, maintenance practices and decision to fly with malfunctioning angle of attack sensors."[112] Muilenburg encouraged Boeing's public relations team to maintain that the 737 MAX was safe, and on December 13, he reported to the Board that "members of our Communications team met with *Wall Street Journal* editors in New York to further discuss ongoing coverage and restate our expectation for fair and fact-based reporting."[113]

2. The Board Formally Addresses The Lion Air Crash For The First Time In December 2018, But Does Not Focus On The 737 MAX's Safety Then Or Thereafter.

After the November 23 optional update, the Board did not formally convene and address the Lion Air Crash until its regularly scheduled Board meetings on December 16 and 17. Consistent with the fact that safety was not a regular topic of Board discussion, the minutes reflect that the Board's primary focus relating to the 737 MAX and Lion Air Crash was on restoring profitability and efficiency in light of longstanding supply chain issues. Over the course of two days, the Board

[112] Am. Compl. ¶ 226.

[113] Defs.' Ex. 60; *see* Am. Compl. ¶ 227.

allocated five total minutes to eight different "Watch Items," one of which was "progress working through supply chain and factory disruption affecting MAX deliveries."[114] The Board allocated another five minutes to reviewing a four-page legal memo "including matters related to the Lion Air incident."[115] And it allocated ten minutes to Compliance Risk Management.[116] The associated risk management report contained one page on the FAA Settlement, which said nothing about the 737 MAX or airplane safety generally.[117] In the Executive Session presentation, the "Lion Air incident" was listed as a "Hot Topic."[118]

The Audit Committee met, too. The material it intended to present to the full Board included an "Ethics and Compliance Update," but did not contain any meaningful information about the 737 MAX's safety or safety generally.[119] An Ethics and Compliance Update presentation dated December 17, 2018, included a chart summarizing "Substantiated Cases" of eight categories of "Inquiries and Investigations," including "Safety, Health & Environmental" alongside "Sexual Harassment," "Proper Use of Co. Time or Resources," and "Information

---

[114] Defs.' Ex. 61 at 2; Defs.' Ex. 84 at -618197, -618203.

[115] Defs.' Ex. 14; Defs.' Ex. 61 at 2; Defs.' Ex. 84 at -618197, -618204–07. That memo was wholly redacted in Defendants' Section 220 production.

[116] Defs.' Ex. 84 at -618197.

[117] *Id*. at -618233.

[118] Am. Compl. ¶ 231.

[119] Defs.' Ex. 84 at -618218–28.

Integrity."[120] The agendas for the Audit Committee's forthcoming 2019 meetings did not indicate any focus on airplane safety.[121] The December 16 and 17 Board meeting did not result in any meaningful action to address airplane safety by either the full Board or the Audit Committee.

The Board next received information about the Lion Air Crash on January 16, 2019, when Muilenburg sent his monthly business summary and competitor dashboard.[122] It began with a one-paragraph "brief update on the ongoing Lion Air flight 610 accident investigation" that was proceeding with Boeing's "full support."[123] Muilenburg also noted that Boeing is "exploring potential 737 MAX software enhancements that, if made, would further improve the safety systems," and maintained that "airlines around the world continue to operate the MAX safely" and were "ma[king] significant new orders and commitments, expressing strong confidence in the airplane."[124] After mentioning safety in passing, Muilenburg moved on to a detailed discussion of the market's confidence in the 737 MAX, and Boeing's "financials" and "strong operating performance and solid cash generation," which were "driven by solid commercial . . . deliveries . . . as well as continued

---

[120] *Id*. at -618225.

[121] *Id*. at -618301.

[122] Am. Compl. ¶ 233; Defs.' Ex. 62.

[123] Defs.' Ex. 62.

[124] *Id*.

focus on productivity."[125] He expressed that Boeing had "set a new industry and company record and validated our team's 737 recovery efforts," and noted that 2019 was "already off to a strong start," as the Company was "focus[ed]" on "driving 737 production line stability and preparation for the 57 aircraft per month rate decision."[126] The dashboard concluded with an overview of political issues affecting the Company.[127]

Muilenburg sent his next monthly business summary and competitor dashboard to the Board on February 13.[128] It did not mention the Lion Air Crash.[129] Muilenburg wrote that Boeing would continue to work with the FAA on a "737 MAX software enhancement that, when implemented, will further improve system safety;" that "[d]espite recent media speculation," nothing had been decided about the "software update and its timing;" and that "[w]e'll keep engaging media and other stakeholders on the merits of the airplane, our processes and our people."[130] It went on:

> And on 737, we're driving production line stability and engaging key suppliers, with a particular focus on CFM engines, as we prepare for a decision later this year on increasing rate to 57 airplanes per month. . . .

---

[125] *Id.*

[126] *Id.*

[127] *Id.*

[128] Am. Compl. ¶ 234; Defs.' Ex. 63.

[129] *See generally* Defs.' Ex. 63.

[130] *Id.* at -13683.

> We remain on track to achieve our quarterly delivery target of 206 planes (including 147 737s), and ramp-up of 737 deliveries in February and March remains an intense focus area.[131]

And it highlighted financials, noting that "Boeing stock [recently] closed at an all-time high."[132]

One week later, on February 20, Executive Vice President and General Counsel Michael Luttig provided a report to the Audit Committee summarizing significant legal matters, including the "Lion Air Accident."[133]

3. The Board Decides To Forego Investigation, And Boeing Belatedly Admits It Deceived The FAA.

The Board next met formally on February 24 and 25. As reflected in the Executive Session presentation, two of the "Other Updates" on "Key Topics" were "737 Production" and "Lion Air Accident."[134] On February 25, the Board issued an addendum to its meeting minutes summarizing a legal update from Luttig.[135] The addendum states that the Board "decided to delay any investigation until the conclusion of the regulatory investigations or until such time as the Board determines that an internal investigation would be appropriate."[136]

---

[131] *Id*. at -13862.

[132] *Id*.

[133] Defs.' Ex. 15. The remainder of that report was redacted in the Section 220 production.

[134] Defs.' Ex. 64 at -575.

[135] Pls.' Ex. 4; Am. Compl. ¶ 238.

[136] Pls.' Ex. 4.

By January 2019, the Department of Justice ("DOJ") had opened a criminal investigation into whether Boeing had defrauded the FAA when obtaining certification of the 737 MAX. In February 2019, Boeing gave the DOJ Forkner's November 2016 text messages admitting he had lied to the FAA.[137] Muilenburg and Luttig were aware of the text messages in the first couple of months of 2019. Muilenburg, Luttig, and Boeing did not provide those text messages to the FAA until October 2019. The FAA demanded an explanation for Forkner's remarks and "Boeing's delay in disclosing the document to its safety regulator."[138]

As stated in Boeing's eventual 2021 agreement with the DOJ, Boeing "did not timely and voluntarily disclose to the Fraud Section the offense conduct described in the Statement of Facts" and Boeing's cooperation "was delayed and only began after the first six months of the Fraud Section's investigation, during which time the Company's response frustrated the Fraud Section's investigation."[139] As a result, Boeing agreed to pay a "Total U.S. Criminal Monetary Amount" of $2.513 billion, composed of a criminal monetary penalty of $243.6 million, compensation payments to Boeing's 737 MAX airline customers of $1.77 billion, and the establishment of a $500 million crash-victim beneficiaries fund.[140]

---

[137] Am. Compl. ¶¶ 10, 235, 290; *id*. Ex. A; *id*. Ex. B.

[138] Pls.' Ex. 5; Am. Compl. ¶ 278.

[139] Am. Compl. Ex. B ¶¶ 4(b)–(c); *id*. ¶¶ 13, 106, 123, 239, 290.

[140] *Id*. ¶ 296; *id*. Ex. B.

4. MCAS Causes The Ethiopian Airlines Crash.

On March 10, less than one month after the Board declined to pursue an internal investigation, another 737 MAX crashed. Ethiopian Airlines Flight ET 302 went down shortly after taking off, killing all 157 passengers and crew. The pilots followed Boeing's recommended emergency procedures, but could not regain control of the plane because MCAS repeatedly activated.

5. Muilenburg Does Damage Control, But The Board Does Not Assess The Safety Of Boeing's Airplanes.

Boeing quickly issued a public statement before authorities released any details about the Ethiopian Airlines Crash. On March 11, the Company emphasized that if the Ethiopian Airlines pilot followed the checklist of procedures in the flight manual, he "[would] always be able to override the flight control using electric trim or manual trim."[141] But by that time, one-third of the world's fleet of in-service 737 MAX aircraft had been grounded, and several United States Senators called for the FAA to ground the 737 MAX.

That same day, Muilenburg emailed the Board. While stating that "[o]ur objective is to ensure our teams are centered on our priorities, including safety, quality and stability,"[142] Muilenburg's comments were not geared toward taking

---

[141] *Id.* ¶ 248.

[142] Defs.' Ex. 66 at -620851.

action to address and improve the 737 MAX's safety. Nor were they made in response to any Board inquiry as to the airplane's safety. Instead, Muilenburg addressed the Board's objectives for the 737 MAX: "ongoing production operations," revenue, and reputational achievement.[143] He advised the Board that management was engaging in extensive outreach with Boeing's customers and regulators to "reinforce our confidence in the 737 MAX."[144] He touted that the FAA had issued a notification reinforcing the 737 MAX's airworthiness, and "mentioned the pending MAX software enhancement with the expectation it will mandate upgrade in April."[145] He concluded by addressing how Boeing intended to handle the Ethiopian Airlines Crash in the media and internal communications, and directed inquiries to Boeing's media relations team.

Thereafter, Muilenburg reviewed and responded to an all-employee email prepared by that team. He thought the note was "solid," but "lack[ed] a statement about our confidence in the fundamental safety of the MAX."[146]

> This goes back to our discussion last night on answering two basic questions: *is the MAX safe? And was MCAS involved? We need to make a strong statement on the first, and be clear that there are no supporting facts on the second*.[147]

---

[143] *Id.*

[144] *Id.*

[145] *Id.*

[146] Am. Compl. ¶ 243.

[147] *Id.*

Muilenburg emailed the Board again on March 12, providing a "quick interim update" before a formal Board call the following day.[148] Muilenburg stated that "[a]s you've seen in the news flow today, additional international authorities have grounded the 737 MAX," but assured the Board that those decisions were driven solely by "public/political pressure, not by any new facts."[149]

During this pivotal period, Boeing was engaged in continuous conversations with the FAA, and Muilenburg spoke with Department of Transportation Secretary Elaine Chao and President Donald Trump in an attempt to keep the 737 MAX flying. On March 12, FAA officials reiterated their position that domestic flights of the 737 MAX would continue. At least one director, Liddy, praised Muilenburg's efforts during this period.[150]

6. The FAA Grounds The 737 MAX, But The Board's Focus Remains On Restoring Boeing's Reputation And Sales.

On March 13, the FAA's investigation of the Ethiopian Airline Crash indicated that the plane experienced the same pattern of repeated steep dives and

---

[148] Defs.' Ex. 68.

[149] *Id.*

[150] Am. Compl. ¶ 252 ("I, for one, really appreciate the strong leadership you're demonstrating in a very challenging situation. Your leadership will prevail.").

climbs caused by MCAS that preceded the Lion Air Crash. The FAA grounded the 737 MAX, becoming the final major aviation regulator to do so.

After the FAA grounded the planes, the Board held a call with management regarding the Ethiopian Airlines Crash and whether Boeing should itself ground the fleet.[151] The Board did not consider, deliberate, or decide on grounding the plane or other immediate remedial measures until after the second crash and the FAA's grounding over Boeing's objection. No Board minutes or agendas between November 2018 and March 2019 reference a discussion about grounding the 737 MAX.

Nonetheless, Boeing jumped at the opportunity to claim credit for the grounding. Later on March 13, Muilenburg told the Board that Boeing had managed to get its own messaging out about the grounding before the FAA released its statement.[152]

That evening, Muilenburg followed up with his monthly business update, which began with his efforts to rehabilitate Boeing's image.[153] In particular, he shared that "Kevin McAllister and I spent time walking the 737 production line in Renton, where we filmed a joint video for team members."[154] With the comment

---

[151] *See* Defs.' Ex. 69; Am. Compl. ¶¶ 255–56.

[152] Defs.' Ex. 69.

[153] Defs.' Ex. 70.

[154] *Id.*

that "safety . . . is our top priority," Muilenburg disclosed that for the first time, he "added safety metrics to our monthly report."[155] This marked one of the first formal implementations of safety reporting to the Board. Muilenburg initiated this update. His addition continued to focus on production, including "year-to-date targets and actuals for lost workday cases, recordable injuries and near misses."[156] His March business summary then turned to the 737 MAX's business performance and ability to meet delivery targets.[157]

Over the next six weeks, Muilenburg's communications to the Board focused on restoring Boeing's reputation and returning the 737 MAX to service. And some Directors' messages to Muilenburg echoed his focus on reputational and production triage. For example, on March 21, Giambastiani emailed Muilenburg to direct him to an article from *Aviation Week* and emphasized a comment suggesting the pilots were at fault for the two crashes.[158] And on March 26, Duberstein emailed Muilenburg to inquire about the reputational impact of an emergency landing of a Southwest 737 MAX due to engine problems, complaining that the report "[l]ed the network news" and was "[a]nother reputational hit at us and no comment from us."[159]

---

[155] *Id.*

[156] *Id.*

[157] *Id.*

[158] Am. Compl. ¶ 259 ("More importantly for the pilot . . . FLY THE PLANE.").

[159] *Id.* ¶ 260.

On April 4, a preliminary report on the Ethiopian Airlines Crash identified MCAS as a contributing cause for the accident. After sending a draft to the full Board, Boeing issued a press release maintaining that most "accidents are caused by a chain of events" and that was the case for the two crashes.[160]

E. In April 2019, The Board Adopts Safety Oversight Measures.

Some directors questioned Boeing's approach. On March 15, Arthur Collins and then-Lead Director David Calhoun recommended a Board meeting devoted to product safety. As Collins explained to Calhoun,

> In light of the two 737 MAX 8 crashes and subsequent global fleet grounding, the previous grounding of Air Force KC-46 tankers, and the Amazon 767 cargo plane crash, I believe we should devote the entire board meeting (other than required committee meetings and reports) to a review of quality within Boeing. This would start with an update on what we know about each of the three previously mentioned situations, but then include a review of quality metrics and actions that are either currently in place or planned to assure that the highest level of quality is designed into all Boeing products or incorporated into all manufacturing, customer training, and service support activities. In addition to providing necessary information for the Board, this type of agenda would underscore the board's (and management's) unwavering commitment to quality and safety above all other performance criteria. I recognize that this type of approach needs to be communicated carefully so as not to give the impression that the board has lost confidence in management (which we haven't) or that there is a systemic problem with quality throughout the corporation (which I don't believe there is), but I'm sure this can be done. . . . I'll leave the decision in your hands with Dennis [Muilenburg].[161]

---

[160] *Id.* ¶ 262.

[161] *Id.* Ex. C.

Collins followed up on the "category of 'lessons learned,'" reminding Calhoun that, at Medtronic (on whose board they both had served), Collins "began each board meeting, executive committee meeting, and operating review with a review of product quality/safety—before any discussion of financial performance, market share/competitive activities, new product development timetables, and certainly stock price."[162] He stressed that people "paid close attention to the priorities of senior management, and everyone in the corporation understood that nothing was more important to the CEO and the board than quality/safety," and that "[i]t's hard to quantify the impact of this approach, but it certainly was important."[163]

Calhoun forwarded Collins's messages to Muilenburg, who responded that it was "[g]ood input"; that he "added Safety data to the Board lead-off briefing, and just added it to my monthly Board note too"; and that "just so you know, Safety data is the first data we look at during our internal ExCo reviews."[164] Thereafter, Muilenburg and Calhoun held a call regarding Collins's suggestions for making safety a Board priority.[165]

At the Board's next regularly scheduled meeting on April 28 and 29, the Board focused on the Ethiopian Airlines Crash and its implications for the Company. In

---

[162] *Id.*

[163] *Id.*

[164] *Id.* I infer "ExCo" refers to management's Executive Council.

[165] *See id.*

contrast to prior Board meetings, the Board dedicated approximately two hours and fifteen minutes to discussing the 737 MAX. For the first time, the Board critically assessed MCAS, the FAA certification process, and pilot training requirements.

The Board also initiated Board-level safety reporting for the first time. On April 4, the Board established the Committee on Airplane Policies and Processes (the "Airplane Committee"). Even then, the Airplane Committee's fact-finding sessions intended to inform the Committee's conclusions and recommendations were sparsely attended: Giambastiani was the sole Board attendee at more than half of the Committee's eighteen fact-finding sessions with internal and external experts, including on topics such as airline training requirements and an overview of BCA's safety process.

Between April and August 2019, the Airplane Committee entertained presentations on seven new topics—including "[c]ommercial airplane design and manufacturing and policies and processes," "aircrew training requirements," and "engineering and safety organizational structures in related industries"—none of which had been the subject of previous Board briefings.[166] For example, in April 2019, Lynne Hopper, Boeing's Vice President of BCA Engineering, and Beth Pasztor, BCA's Vice President of Safety, Security & Compliance, presented to the Board for the first time.

---

[166] *Id.* ¶ 70.

On May 6, for the first time, the Airplane Committee formally requested information about the cause of the crashes. As Committee chair, Giambastiani asked Hyslop to provide information about pilot training requirements, Boeing's "Quick Action" checklists for emergencies, and airlines that had purchased an AOA disagree alert.[167] And in late June, Giambastiani proposed that product safety reports evaluated by the SRB "should feed to [A]udit [C]ommittee" and "should go to CTO/CFO and [be] shared with Board"; that the Audit Committee should have "visibility of high risk issues"; and that "the entire list of safety issues on the MAX [should be] reported to Dennis [Muilenburg]/Greg [Hyslop]."[168]

The Airplane Committee also recommended that the Board establish another committee dedicated to safety. And so on August 26, the Board established the Aerospace Safety Committee "for the purpose of assisting the Board in the oversight of the safe design, development, manufacture, production, operations, maintenance, and delivery of the aerospace products and services of the Company."[169] It was also responsible for overseeing the airplane certification process and Company protocols for engaging with the FAA. In turn, the Aerospace Safety Committee quickly recommended that the Board create yet another oversight committee. On September

---

[167] *Id.* ¶ 72.

[168] *Id.* ¶ 81 (alteration in original).

[169] *Id.* ¶ 73.

30, the Board created a Product and Services Safety Organization that was responsible for, among other things, investigating "cases of undue pressure and anonymous product and service safety concerns raised by employees," and represented Boeing's first mechanism or reporting line to convey employee complaints to the Board.[170]

Product safety reporting processes up to executives and the Board were operational by October 20. And at the December 15 Board meeting, the Audit Committee received a compliance risk management report from chief compliance and ethics officer Sands that, for the first time, included a category for "Safety." In comparison, Sands's report from the December 2018 Board meeting following the Lion Air Crash had not covered product safety at all.

Muilenburg also embraced the new focus on safety. In an email to McAllister, Hyslop, Smith, and other senior Boeing officials, he wrote,

> As *part of our lessons learned from the MAX, we need to have a clear understanding of how safety risk is being assessed*, and appropriately "test" those items that are assessed as "medium" or at a "minor" or "major" hazard level to ensure the right visibility/action/communication. . . . This is an exceptionally important process improvement area for us all.[171]

---

[170] *Id.* ¶ 93.

[171] *Id.* ¶ 82.

By late 2019, Muilenburg began receiving "granular weekly reports of potential safety issues discussed at meetings of rank-and-file engineers - something that did not happen in the past."[172] And Muilenburg eventually acknowledged that access to better information would have supported grounding the 737 MAX fleet shortly after the Lion Air Crash.[173]

F. The Board Attempts To Preserve Its Image, Despite Eschewing Safety Oversight Initiatives Until April 2019.

The Board publicly lied about if and how it monitored the 737 MAX's safety. As the Board was establishing formal safety monitoring processes, then-Lead Director Calhoun held a series of interviews with major newspapers with the following corporate objective: "Position the Boeing Board of Directors as an independent body that has exercised appropriate oversight."[174] As to the Lion Air Crash, Calhoun represented that the Board had been "notified immediately, as a board broadly," after the Lion Air crash and met "very, very quickly" thereafter;[175] participated in evaluating the safety risk associated with the 737 MAX; and considered grounding the 737 MAX after the Lion Air Crash, but concluded the

---

[172] *Id.* ¶ 83.

[173] *Id.* ¶ 84 ("[I]f we knew back then what we know now, we would have grounded right after the first accident.").

[174] *Id.* ¶ 263.

[175] *Id.* ¶¶ 268–69.

crash "was an anomaly" that did not warrant grounding the airplane.[176] As to the Ethiopian Airlines Crash, Calhoun represented that the Board met within twenty-four hours of the crash to discuss potential grounding of the 737 MAX and recommended that the 737 MAX be grounded. Each of Calhoun's representations was false.

In addition, Calhoun and the Board would publicly denounce Muilenburg. Muilenburg had come under fire from the FAA, but as of November 5, 2019, Calhoun maintained that, "[f]rom the vantage point of our board, Dennis has done everything right."[177] With additional scrutiny, regulators learned the extent of Boeing's deceit under Muilenburg's leadership, and the FAA came down on him. On December 22, after learning that the FAA had reprimanded Muilenburg and after *The New York Times* published an article reporting on his deficiencies, the Board called a meeting and voted to terminate Muilenburg and replace him with Calhoun, "to restore confidence in the Company moving forward as it works to repair relationships with regulators, customers, and all other stockholders."[178]

The Board did not terminate Muilenburg for cause, and publicly characterized his departure as his "resignation," and later as his "retirement."[179] In doing so, the

---

[176] *Id.* ¶ 271.

[177] *Id.* ¶ 280.

[178] *Id.* ¶¶ 284–85.

[179] *Id.* ¶¶ 288–89.

Board enabled Muilenburg to retain unvested equity awards worth approximately $38,642,304.[180] The Board also announced that Luttig would "retire," allowing him to keep his unvested equity awards as well.[181] As alleged, the Board chose this path because "[a]ny public dispute between Boeing and Muilenburg would have exposed the Board's prolonged support of Muilenburg and lack of safety oversight."[182]

Calhoun became CEO in January 2020. In that role, he publicly questioned Muilenburg's leadership, shifting blame away from the Board. Calhoun stated that the Board "never seriously questioned [Muilenburg's] strategy, in part because before the first MAX crash off the coast of Indonesia in October 2018, the company was enjoying its best run in years," and painted Muilenburg as a money-hungry leader that was willing to prioritize profits over quality and safety.[183] In Calhoun's words, "If [the Board] w[as] complacent in any way, maybe, maybe not, I don't know. . . . We supported a C.E.O. who was willing and whose history would suggest that he might be really good at taking a few more risks."[184]

---

[180] *Id.* ¶ 286.

[181] *Id.* ¶ 289.

[182] *Id.* ¶ 287.

[183] *Id.* ¶ 291 (quoting a *New York Times* article as stating, "[Calhoun had] never be able to judge what motivated [Muilenburg], whether it was a stock price that was going to continue to go up and up, or whether it was just beating the other guy to the next rate increase," and that "[i]f anybody ran over the rainbow for the pot of gold on stock, it would have been [Muilenburg]").

[184] *Id.* (alterations in original).

G. Corporate Trauma Inspires This Suit.

The 737 MAX fleet was grounded for twenty months, until November 18, 2020. During that period, Boeing was federally mandated to cure the defects in the 737 MAX's MCAS system and AOA sensor and to revamp pilot training. But these measures did not rectify the significant damage the Lion Air and Ethiopian Airlines Crashes and the 737 MAX Grounding caused to Boeing's profitability, credibility, reputation, and business prospects. Nor did they unwind Boeing's exposure to substantial criminal, regulatory, and civil liability. In 2020, Boeing estimated that it had incurred non-litigation costs of $20 billion, and litigation-related costs in excess of $2.5 billion. Litigation continues on multiple fronts, and customers cancelled orders. And in January 2021, Boeing consented to the filing of a criminal information charging the Company with conspiracy to defraud the United States and thereby incurring billions of dollars in penalties.[185]

The corporate harm Boeing suffered inspired numerous books and records requests and derivative actions filed in this Court in 2019. The Court consolidated the plenary actions and appointed NYSCRF and FPPA as Co-Lead Plaintiffs on August 3, 2020.[186] Plaintiffs filed the Verified Amended Consolidated Complaint on January 29, 2021 (the "Amended Complaint"), addressing the DOJ's criminal

---

[185] *Id.* ¶ 11; Am. Compl. Ex. B.

[186] D.I. 88.

penalties.[187] Count I asserts a derivative claim for breach of fiduciary duty against the Director Defendants, alleging they consciously breached their fiduciary duties and violated their corporate responsibilities by (1) before the Lion Air Crash, failing to implement any reasonable information and reporting system to monitor and oversee the safety of Boeing's airplanes; (2) after the Lion Air Crash, despite being made aware of red flags concerning the operation, development, and nondisclosure of MCAS, consciously disregarding their duty to investigate and to remedy any misconduct uncovered; and (3) after the Ethiopian Airlines Crash, falsely assuring the public about the safety of the 737 MAX and MCAS and deciding to cash out Muilenburg's unvested equity-based compensation.[188] Count II asserts a derivative claim for breach of fiduciary duty against the Officer Defendants, alleging they consciously breached their fiduciary duties or, at a minimum, acted with gross

---

[187] *See generally* Am. Compl.

[188] *Id.* ¶ 305. Plaintiffs originally alleged that the Director Defendants breached their fiduciary duties before the Lion Air Crash by ignoring several red flags concerning airplane safety. *Id.* At oral argument, Plaintiffs shifted this theory. *See* Hr'g Tr. 135–36 ("MR. FRIEDLANDER: Frankly, Your Honor, I think it's better not to think of those as red flags for *Marchand* in the sense of that -- like *Marchand* never uses the concept of red flags. . . . I would say these are points of emphasis to illustrate the problems that the reporting system had . . . because there's an affirmative obligation to create a reporting system of the type described in *Marchand*. We're saying they didn't do it, and then we said which *Marchand* requires. And as a second argument, and they had red flags and nonetheless they still didn't do it. But really it's all incorporated under the affirmative obligation of *Marchand* to create it. THE COURT: So you would like me to look at those more under prong one as a deficient reporting system [rather] than under prong two, red flags? MR. FRIEDLANDER: Yeah. But I think they're important . . . .").

negligence by (1) consciously and repeatedly failing to implement and actively monitor or oversee a compliance and safety program; (2) consciously disregarding their duty to investigate red flags and to remedy any misconduct uncovered; and (3) covering up the extreme safety risks of Boeing's aircraft.

On March 19, Defendants moved to dismiss pursuant to Court of Chancery Rules 12(b)(6) and 23.1 (the "Motion").[189] Defendants submitted eighty-eight exhibits in support of the Motion.[190] The parties briefed the Motion as of June 4.[191] I heard argument on June 25 and took the Motion under advisement.[192]

II. ANALYSIS

Defendants have moved to dismiss all claims against them pursuant to Court of Chancery Rule 23.1 for failure to plead that demand is futile.

Plaintiffs assert Defendants' breaches of fiduciary duty harmed Boeing. Thus, the claims belong to Boeing and the decision whether to pursue the claim presumptively lies with the Board.[193] But our law recognizes that, "[i]n certain

---

[189] D.I. 145; D.I. 146.

[190] D.I. 147; D.I. 148; D.I. 149; D.I. 150; D.I. 151; D.I. 152; D.I. 160.

[191] D.I. 146; D.I. 155; D.I. 159.

[192] D.I. 167; Hr'g Tr.

[193] *White v. Panic*, 783 A.2d 543, 550 (Del. 2001) ("In most situations, the board of directors has sole authority to initiate or to refrain from initiating legal actions asserting rights held by the corporation."); *see Aronson v. Lewis*, 473 A.2d 805, 811 (Del. 1984) ("A cardinal precept of the General Corporation Law of the state of Delaware is that directors, rather than shareholders, manage the business and affairs of the corporation."), *overruled on other grounds by Brehm v. Eisner*, 746 A.2d 244 (Del. 2000).

circumstances, stockholders may pursue litigation derivatively on behalf of the corporation as a matter of equity to redress the conduct of a torpid or unfaithful management . . . where those in control of the company refuse to assert (or are unfit to consider) a claim belonging to it."[194] "Because stockholder derivative suits by [their] very nature . . . impinge on the managerial freedom of directors, our law requires that a stockholder satisfy the threshold demand requirements of Court of Chancery Rule 23.1 before he is permitted to assume control of a claim belonging to the corporation."[195]

Rule 23.1 requires pleadings to "comply with stringent requirements of factual particularity that differ substantially from the permissive notice pleadings governed solely by Chancery Rule 8(a)."[196] To satisfy Rule 23.1, the stockholder must plead with particularity either that she made a demand on the company's board of directors to pursue particular claims and was refused, or why any such demand would be futile, thereby excusing the need to make a demand altogether.[197] Where, as here,

---

[194] *In re CBS Corp. S'holder Class Action & Deriv. Litig.*, 2021 WL 268779, at *27 (Del. Ch. Jan. 27, 2021), *as corrected* (Feb. 4, 2021) (quoting *Cumming v. Edens*, 2018 WL 992877, at *11 (Del. Ch. Feb. 20, 2018) (internal quotation marks omitted)).

[195] *Horman v. Abney*, 2017 WL 242571, at *6 (Del. Ch. Jan. 19, 2017) (quoting *Aronson*, 473 A.2d at 811) (internal quotation marks omitted).

[196] *Brehm*, 746 A.2d at 254; *accord In re Citigroup Inc. S'holder Deriv. Litig.*, 964 A.2d 106, 120–21 (Del. Ch. 2009).

[197] *Beam ex rel. Martha Stewart Living Omnimedia, Inc. v. Stewart*, 845 A.2d 1040, 1044 (Del. 2004); *Wood v. Baum*, 953 A.2d 136, 140 (Del. 2008).

the stockholder plaintiff foregoes a demand on the board, she "must plead particularized facts creating a reasonable doubt concerning the Board's ability to consider the demand."[198]

Demand futility turns on "whether the board that would be addressing the demand can impartially consider [the demand's] merits without being influenced by improper considerations."[199] While the continued utility of a binary approach to demand futility has been called into question, for now, Delaware still applies one of two tests when deciding whether demand upon the board would be futile.[200] The first, established in *Aronson v. Lewis*, "applies to claims involving a contested transaction i.e., where it is alleged that the directors made a conscious business decision in breach of their fiduciary duties."[201] The second, established in *Rales v.*

---

[198] *CBS*, 2021 WL 268779, at *28; *Citigroup*, 964 A.2d at 121 ("Demand is not excused solely because the directors would be deciding to sue themselves. Rather, demand will be excused based on a possibility of personal director liability only in the rare case when a plaintiff is able to show director conduct that is so egregious on its face that board approval cannot meet the test of business judgment, and a substantial likelihood of director liability therefore exists." (footnotes and internal quotation marks omitted)).

[199] *Rales v. Blasband*, 634 A.2d 927, 934 (Del. 1993).

[200] *See United Food & Commerc. Workers Union v. Zuckerberg*, 250 A.3d 862, 877 (Del. Ch. 2020) (observing that "the *Aronson* test has proved to be comparatively narrow and inflexible in its application, and its formulation has not fared well in the face of subsequent judicial developments").

[201] *Wood*, 953 A.2d at 140 (citing *Aronson*, 473 A.2d at 814) (explaining the two demand futility tests). Under *Aronson*, the plaintiff must plead particularized facts that create a reasonable doubt that (i) the directors are disinterested and independent or (ii) the challenged transaction was otherwise the product of a valid exercise of business judgment. *Id.*

Blasband,[202] applies where a majority of the current members of the board "had not participated in the challenged decision,"[203] or "where the subject of a derivative suit is not a business decision . . . [such as when the board is alleged to have violated its] oversight duties."[204]

Here, the parties agree that *Rales* governs.[205] "The central question of a *Rales* inquiry, no matter the context, is the same: 'whether the board can exercise its business judgment on the corporate behalf in considering demand.'"[206] In refining that question, *Rales* instructs that a director cannot objectively exercise her business judgment in considering a demand if she is either (1) "interested," meaning, among other things, that she faces a "substantial likelihood of liability" for her role in the alleged corporate wrongdoing; or (2) not independent of another interested fiduciary.[207]

---

[202] 634 A.2d at 927.

[203] *Zuckerberg*, 250 A.3d at 887.

[204] *Wood*, 953 A.2d at 140; *see also Horman*, 2017 WL 242571, at *6 (holding that *Rales* applies "when a plaintiff challenges board inaction such as when a board is alleged to have consciously disregarded its oversight duties").

[205] *See* D.I. 146 at 58 ("Whether the Board's decision to terminate Muilenburg is considered under *Aronson* or *Rales*, . . . Plaintiffs fail to establish demand futility." (citing *Zuckerberg*, 2020 WL 6266162, at *9–18)); *id.* at 60 (assessing Plaintiffs' claims under *Rales*); D.I. 155 at 38 (citing and applying *Rales*).

[206] *McElrath ex rel. Uber Techs. v. Kalanick*, 2019 WL 1430210, at *8 (Del. Ch. Apr. 1, 2019) (quoting *Inter-Mktg. Gp. USA, Inc. v. Armstrong*, 2019 WL 417849, at *4 (Del. Ch. Jan. 31, 2019)), *aff'd sub nom. McElrath v. Kalanick*, 224 A.3d 982 (Del. 2020).

[207] *Rales*, 634 A.2d at 934, 936 (noting that, at bottom, the court must "determine whether or not the particularized factual allegations of a derivative stockholder complaint create a

"On a motion to dismiss pursuant to Rule 23.1, the Court considers the same documents, similarly accepts well-pled allegations as true, and makes reasonable inferences in favor of the plaintiff—all as it does in considering a motion to dismiss under Rule 12(b)(6)."[208] Given the heightened pleading requirements of Rule 23.1, however, "conclusory allegations of fact or law not supported by allegations of specific fact may not be taken as true."[209] "Because of the absence of a precise formula in the Rule for pleading compliance with the demand requirement, the sufficiency of a complaint under Rule 23.1 is determined on the basis of the facts of each case."[210]

"Rule 23.1 does not abrogate Rule 12(b)(6)."[211] But because "the standard under Rule 12(b)(6) is less stringent than the standard under Rule 23.1, a complaint that survives a Rule 23.1 motion to dismiss generally will also survive a Rule

---

reasonable doubt that, as of the time the complaint is filed, the board of directors could have properly exercised its independent and disinterested business judgment in responding to a demand"); *CBS*, 2021 WL 268779, at *28 (same); *In re Clovis Oncology, Inc. Deriv. Litig.*, 2019 WL 4850188, at *11 (Del. Ch. Oct. 1, 2019) (stating that when board oversight is challenged, "such improper influence arises if a majority of the board's members are compromised because [] they face a substantial likelihood of personal liability with respect to at least one of the alleged claims" (internal quotation marks omitted)).

[208] *Beam*, 833 A.2d at 976 (Del. Ch. 2003) (citing *White*, 783 A.2d at 549), *aff'd*, 845 A.2d 1040 (Del. 2004).

[209] *Grobow v. Perot*, 539 A.2d 180, 187 (Del. 1988), *overruled on other grounds by Brehm*, 746 A.2d at 244.

[210] *Brehm*, 746 A.2d at 268 (Hartnett, J. concurring).

[211] *Id*.

12(b)(6) motion to dismiss, assuming that it otherwise contains sufficient facts to state a cognizable claim."[212] The standards governing a motion to dismiss under Court of Chancery Rule 12(b)(6) for failure to state a claim for relief are well settled:

> (i) all well-pleaded factual allegations are accepted as true; (ii) even vague allegations are "well-pleaded" if they give the opposing party notice of the claim; (iii) the Court must draw all reasonable inferences in favor of the non-moving party; and ([iv]) dismissal is inappropriate unless the "plaintiff would not be entitled to recover under any reasonably conceivable set of circumstances susceptible to proof."[213]

Thus, the touchstone "to survive a motion to dismiss is reasonable 'conceivability.'"[214] This standard is "minimal"[215] and plaintiff-friendly.[216] "Indeed, it may, as a factual matter, ultimately prove impossible for the plaintiff to prove his claims at a later stage of a proceeding, but that is not the test to survive a motion to dismiss."[217] Despite this forgiving standard, the Court need not "accept conclusory allegations unsupported by specific facts" or "draw unreasonable

---

[212] *In re Walt Disney Co. Deriv. Litig.*, 825 A.2d 275, 285 (Del. Ch. 2003).

[213] *Savor, Inc. v. FMR Corp.*, 812 A.2d 894, 896–97 (Del. 2002) (citations omitted).

[214] *Cent. Mortg. Co. v. Morgan Stanley Mortg. Cap. Hldgs. LLC*, 27 A.3d 531, 537 (Del. 2011).

[215] *Id.* at 536 (citing *Savor*, 812 A.2d at 896).

[216] *See, e.g.*, *Clouser v. Doherty*, 175 A.3d 86 (Del. 2017) (TABLE); *In re USG Corp. S'holder Litig.*, 2021 WL 930620, at *3–4 (Del. Ch. Mar. 11, 2021).

[217] *Cent. Mortg. Co.*, 27 A.3d at 536.

inferences in favor of the non-moving party."[218] "Moreover, the court is not required to accept every strained interpretation of the allegations proposed by the plaintiff."[219]

I conclude that (1) Plaintiffs have pled facts sufficient to render demand futile for claims against the Director Defendants, with one carveout, but (2) Plaintiffs have failed to plead demand futility for the claims against the Officer Defendants. Accordingly, the Motion is granted and denied in part as to Count I, and granted as to Count II.

A. With One Exception, Plaintiffs Have Pled That Demand Is Futile For Claims Against The Director Defendants.

For Count I, Plaintiffs assert demand is futile because "from at least November 18, 2019 (the date of filing of the first derivative complaint alleging demand futility) through and including today, a majority of the members of the Board have faced a substantial likelihood of liability for failing to make any good faith effort to implement and oversee a board-level system to monitor and report on safety."[220] At bottom, Plaintiffs' position is that nine of the twelve board members

---

[218] *Price v. E.I. du Pont de Nemours & Co.*, 26 A.3d 162, 166 (Del. 2011), (citing *Clinton v. Enter. Rent-A-Car Co.*, 977 A.2d 892, 895 (Del. 2009)), *overruled on other grounds by Ramsey v Ga. S. Univ. Advanced Dev. Ctr.*, 189 A.3d 1255 (Del. 2018).

[219] *In re Trados Inc. S'holder Litig.*, 2009 WL 2225958, at *4 (Del. Ch. July 24, 2009) (internal quotation marks omitted) (quoting *In re Gen. Motors (Hughes) S'holder Litig.*, 897 A.2d 162, 168 (Del. 2006)).

[220] Am. Compl. ¶ 299.

at the time the original complaint was filed[221] face a substantial likelihood of liability for failure to fulfill their oversight duties under the standards set forth in *Caremark*,[222] as applied by the Delaware Supreme Court in *Marchand*.[223]

As Chancellor Allen first observed in *Caremark*, and as since emphasized by this Court many times, perhaps to redundance,[224] the claim that corporate fiduciaries have breached their duties to stockholders by failing to monitor corporate affairs is "possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment."[225] A decade after *Caremark*, our Supreme Court affirmed the doctrine Chancellor Allen announced there and clarified that our law will hold directors personally liable only where, in failing to oversee the operations of the company, "the directors knew that they were not discharging their fiduciary

---

[221] *Id*. ¶¶ 22–43; *see id*. ¶ 301 (alleging that when the original complaint was filed, six of the twelve Board members had served for at least five years before the 2019 Ethiopian Airlines Crash); D.I. 146 at 6 n.2 (detailing changes on the Board since the original complaint was filed).

[222] 698 A.2d 959.

[223] 212 A.3d 805.

[224] *See Chou*, 2020 WL 5028065, at *1 ("It has become among the hoariest of Chancery clichés for an opinion to note that a derivative claim against a company's directors, on the grounds that they have failed to comply with oversight duties under *Caremark*, is among the most difficult of claims in this Court to plead successfully.").

[225] *Caremark*, 698 A.2d at 967; *Globis P'rs, L.P. v. Plumtree Software, Inc.*, 2007 WL4292024, at *7 (Del. Ch. Nov. 30, 2007) (same); *Desimone v. Barrows*, 924 A.2d 908, 939 (Del. Ch. 2007) (same); *Guttman v. Huang*, 823 A.2d 492, 506 n.33 (Del. Ch. 2003) (same).

obligations."[226] At the pleading stage, a plaintiff must allege particularized facts that satisfy one of the necessary conditions for director oversight liability articulated in *Caremark*: either that (1) "the directors utterly failed to implement any reporting or information system or controls"; or (2) "having implemented such a system or controls, [the directors] consciously failed to monitor or oversee its operations thus disabling themselves from being informed of risks or problems requiring their attention."[227] I respectfully refer to these conditions as *Caremark* "prong one" and "prong two."

"Delaware courts routinely reject the conclusory allegation that because illegal behavior occurred, internal controls must have been deficient, and the board must have known so."[228] Rather, the plaintiff must plead with particularity "a sufficient connection between the corporate trauma and the board."[229] "To be sure, even in this context, *Caremark* does not demand omniscience."[230] But it does mandate that "to satisfy their duty of loyalty, directors must make a good faith effort to implement an oversight system and then monitor it."[231]

---

[226] *Stone v. Ritter*, 911 A.2d 362, 370 (Del. 2006).

[227] *Id*.

[228] *Desimone*, 924 A.2d at 940.

[229] *La. Mun. Police Emps.' Ret. Sys. v. Pyott*, 46 A.3d 313, 340 (Del. Ch. 2012), *rev'd on other grounds*, 74 A.3d 612 (Del. 2013).

[230] *Clovis*, 2019 WL 4850188, at *13.

[231] *Marchand*, 212 A.3d at 821.

The *Caremark* standard "draws heavily upon the concept of director failure to act in good faith,"[232] and does not constitute a freestanding fiduciary duty that could independently give rise to liability.[233] Because "[t]he test is rooted in concepts of bad faith," "a showing of bad faith is a *necessary condition* to director oversight liability."[234] As our Supreme Court explained in *In re Walt Disney Co. Derivative Litigation*, the "intentional dereliction of duty" or "conscious disregard for one's responsibilities," which "is more culpable than simple inattention or failure to be informed of all facts material to the decision," reflects that directors have acted in bad faith and cannot avail themselves of defenses grounded in a presumption of good faith.[235] In order to plead a derivative claim under *Caremark*, therefore, a plaintiff must plead particularized facts that allow a reasonable inference the directors acted with scienter which in turn "requires [not only] proof that a director acted

---

[232] *Stone*, 911 A.2d at 369.

[233] *Citigroup*, 964 A.2d at 122–23.

[234] *Id*. at 123.

[235] 906 A.2d 27, 66 (Del. 2006); *Citigroup*, 964 A.2d at 125 ("[O]ne can see a similarity between the standard for assessing oversight liability and the standard for assessing a disinterested director's decision under the duty of care when the company has adopted an exculpatory provision pursuant to § 102(b)(7). In either case, a plaintiff can show that the director defendants will be liable if their acts or omissions constitute bad faith. A plaintiff can show bad faith conduct by, for example, properly alleging particularized facts that show that a director *consciously* disregarded an obligation to be reasonably informed about the business and its risks or *consciously* disregarded the duty to monitor and oversee the business.").

inconsistent[ly] with his fiduciary duties," but also "most importantly, that the director knew he was so acting."[236]

1. The Motion Is Denied In Part As To Count I; Plaintiffs Have Pled Particularized Facts Demonstrating A Majority Of The Director Defendants Face A Substantial Likelihood Of *Caremark* Liability.

Plaintiffs' *Caremark* theory breaks the Company's 737 MAX trauma into three periods of time: before the first crash, between the two crashes, and after the second crash. As crystallized at argument, Plaintiffs' theory before the Lion Air Crash maps onto *Caremark*'s first prong, asserting the Board utterly failed to implement any reporting or information systems or controls.[237] Plaintiffs further assert the first Lion Air Crash was a red flag the Board ignored under prong two, while continuing to fall short under prong one. Plaintiffs contend the Board's prong two deficiencies culminated in the Ethiopian Airlines Crash. And after both crashes, Plaintiffs assert the Director Defendants breached their fiduciary duties by allowing Muilenburg to retire with his unvested equity compensation. Plaintiffs have

---

[236] *In re Massey Energy Co.*, 2011 WL 2176479, at *22 (Del. Ch. May 31, 2011) (emphasis omitted); *Citigroup*, 964 A.2d at 123 ("[T]o establish oversight liability a plaintiff must show that the directors *knew* they were not discharging their fiduciary obligations or that the directors demonstrated a *conscious* disregard for their responsibilities such as by failing to act in the face of a known duty to act.").

[237] *See* Hr'g Tr. 135–36.

sufficiently alleged the Director Defendants face a substantial likelihood of liability under their *Caremark* theories, but not with regard to Muilenburg's compensation.

a. Plaintiffs Have Stated A Claim Under *Caremark* Prong One.

Directors may use their business judgment to "design context- and industry-specific approaches tailored to their companies' businesses and resources. But *Caremark* does have a bottom-line requirement that is important: the board must make a good faith effort—*i.e.*, try—to put in place a reasonable board-level system of monitoring and reporting."[238] This oversight obligation is "designed to ensure reasonable reporting and information systems exist that would allow directors to know about and prevent wrongdoing that could cause losses for the Company."[239] "[O]nly a sustained or systematic failure of the board to exercise oversight—such as an utter failure to attempt to assure a reasonable information and reporting system exists—will establish the lack of good faith that is a necessary condition to liability."[240]

Our Supreme Court's recent decision in *Marchand* addressed the contours of a *Caremark* prong one claim when the company is operating in the shadow of

---

[238] *Marchand*, 212 A.3d at 821 (footnote omitted).

[239] *Citigroup*, 964 A.2d at 131.

[240] *Id*. at 122 (internal quotation marks omitted).

"essential and mission critical" regulatory compliance risk.[241] Distinct from many *Caremark* cases evaluating the company's systems to monitor financial wrongdoing like accounting fraud,[242] *Marchand* addressed the regulatory compliance risk of food safety and the failure to manage it at the board level, which allegedly allowed the company to distribute mass quantities of ice cream tainted by *listeria*. Food safety was the "most central safety and legal compliance issue facing the company."[243] In the face of risk pertaining to that issue, *Marchand* noted the board's oversight function "must be more rigorously exercised."[244] This "entails a sensitivity to compliance issues intrinsically critical to the company."[245]

Marchand held the board had not made a "good faith effort to put in place a reasonable system of monitoring and reporting" when it left compliance with food safety mandates to management's discretion, rather than implementing and then overseeing a more structured compliance system.[246] The Court considered the

---

[241] *Marchand*, 212 A.3d at 824; *see Clovis*, 2019 WL 4850188, at *12.

[242] *E.g.*, *Stone*, 911 A.2d 362; *Hughes*, 897 A.2d 162; *Citigroup*, 964 A.2d 106.

[243] *Marchand*, 212 A.3d at 824 (stating "food safety was essential and mission critical"); *see also id.* at 822 (observing that food safety "has to be one of the most central issues at the company" and "a compliance issue intrinsically critical to the company's [monoline] business operation").

[244] *Clovis*, 2019 WL 4850188, at *13 (citing *Marchand*, 212 A.3d at 824).

[245] *Id.* (alterations, footnotes, internal quotation marks omitted) (quoting *Marchand*, 212 A.3d at 822).

[246] *Marchand*, 212 A.3d at 821–24.

absence of various board-level structures "before the *listeria* outbreak engulfed the company."[247] The Court concluded that the complaint fairly alleged several dispositive deficiencies:

- no board committee that addressed food safety existed;
- no regular process or protocols that required management to keep the board apprised of food safety compliance practices, risks, or reports existed;
- no schedule for the board to consider on a regular basis, such as quarterly or biannually, any key food safety risks existed;
- during a key period leading up to the deaths of three customers, management received reports that contained what could be considered red, or at least yellow, flags, and the board minutes of the relevant period revealed no evidence that these were disclosed to the board;
- the board was given certain favorable information about food safety by management, but was not given important reports that presented a much different picture; and
- the board meetings are devoid of any suggestion that there was any regular discussion of food safety issues.[248]

Like food safety in *Marchand*, airplane safety "was essential and mission critical" to Boeing's business,[249] and externally regulated.[250] Considering

---

[247] *Id*. at 822.

[248] *Id*.

[249] *Id*. at 824.

[250] *See Chou*, 2020 WL 5028065, at *18 ("[W]hen regulations governing drug health and safety are at issue, ABC's Board must actively exercise its oversight duties in order to properly discharge its duties in good faith. The allegations here are a prime example: flouting laws meant to ensure the safety and purity of drugs destined for patients suffering from cancer is directly inimical to the central purpose of ABC's business."); *Clovis*, 2019 WL 4850188, at *13 ("[W]hen a company operates in an environment where externally imposed regulations govern its 'mission critical' operations, the board's oversight function must be more rigorously exercised.").

Marchand's mandate that the board rigorously exercise its oversight function with respect to mission critical aspects of the company's business, such as the safety of its products that are widely distributed and used by consumers, as well as the failings *Marchand* identified as giving rise to the reasonable inference that the board faced a substantial likelihood of liability under prong one, I conclude that Plaintiffs have carried their burden under Rule 23.1 for their prong one claim. To be clear, I do not track the deficiencies *Marchand* identified because they are any sort of prescriptive list; "[a]s with any other disinterested business judgment, directors have great discretion to design context- and industry-specific approaches tailored to their companies' businesses and resources."[251] I echo *Marchand* because it is dispositive in view of Plaintiffs' remarkably similar factual allegations.

i. The Board had no committee charged with direct responsibility to monitor airplane safety.

The Amended Complaint alleges the Board had no committee charged with direct responsibility to monitor airplane safety. While the Audit Committee was charged with "risk oversight," safety does not appear in its charter. Rather, its oversight function was primarily geared toward monitoring Boeing's financial risks.[252]

---

[251] *Marchand*, 212 A.3d at 821.

[252] *See* Hr'g Tr. 30–33.

Perhaps because the Audit Committee was not asked to do so, the pleading stage record indicates the Audit Committee did not regularly or meaningfully address or discuss airplane safety. The yearly report the Audit Committee received on Boeing's compliance risk management process did not include oversight of airplane safety.[253] Specifically as to the 737 MAX, the Audit Committee never assessed its safety risks, including those regarding MCAS and the AOA sensor, during its development before the Lion Air Crash or after; nor did the Audit Committee ask for presentations or information on the topic.[254] Similarly, the ERV process and Corporate Audit group did not address airplane safety.[255]

Defendants press that the Audit Committee addressed "risk" broadly, pointing to one-off instances like when it responded to FAA questions about the Dreamliner battery incident, or when it referred to "quality" or "safety" in passing. But those occasional occurrences fail to dislodge Plaintiffs' allegations that the Board did not specifically charge the Audit Committee with monitoring airplane safety. And to the extent Defendants point to risk analysis mechanisms and reports, like the ERV process and the Corporate Audit group,[256] in the absence of any allegation or

---

[253] Hr'g Tr. 20–23.

[254] *Id*. 32.

[255] *See supra* notes 31–32.

[256] *See* Defs.' Ex. 7; Defs.' Ex. 9; Defs.' Ex. 10; Defs.' Ex. 23; Defs.' Ex. 24; Defs.' Ex. 25.

indication that they were devoted to airplane safety, the reasonable inference is that they fall within the Audit Committee's financial and regulatory risk mandate.

At the pleading stage, the existence of the Audit Committee, Corporate Audit group, and ERV process cannot support the conclusion that the Board established any committee or process charged with direct responsibility to monitor airplane safety. To the contrary, the Board did not establish the Airplane Committee, which was explicitly tasked with overseeing airplane safety, until April 2019; the Airplane Committee was the first Board committee to formally request information about the cause of the crashes.

The lack of Board-level safety monitoring was compounded by Boeing's lack of an internal reporting system by which whistleblowers and employees could bring their safety concerns to the Board's attention. More than three months after the Ethiopian Airlines Crash, Giambastiani proposed that once safety concerns were evaluated by the SRB, they should be elevated to the Audit Committee, CTO, and CFO, and thereafter be shared with the Board.

ii. The Board did not monitor, discuss, or address airplane safety on a regular basis.

Zooming out from the committee level, Plaintiffs have alleged specific facts supporting the conclusion that the Board writ large did not formally address or monitor safety. The Board did not regularly allocate meeting time or devote

discussion to airplane safety and quality control until after the second crash. Nor did the Board establish a schedule under which it would regularly assess airplane safety to determine whether legitimate safety risks existed.

The period after the Lion Air Crash is emblematic of these deficiencies. The Board's first call on November 23 was explicitly optional. The crash did not appear on the Board's formal agenda until the Board's regularly scheduled December meeting; those board materials reflect discussion of restoration of profitability and efficiency, but not product safety, MCAS, or the AOA sensor.[257] The Audit Committee devoted slices of five-minute blocks to the crash, through the lens of supply chain, factory disruption, and legal issues—not safety.[258]

The next board meeting, in February 2019, addressed factory production recovery and a rate increase, but not product safety or MCAS.[259] At that meeting, the Board affirmatively decided to delay its investigation into the 737 MAX, notwithstanding publicly reported concerns about the airplane's safety. Weeks later, after the Ethiopian Airlines Crash,[260] the Board still did not consider the 737 MAX's

---

[257] *See id.* ¶¶ 230–31; Defs.' Ex. 61; *see also* Defs.' Ex. 64 at -575 (identifying the Lion Air Crash as a "key topic" with no mention of safety).

[258] Defs.'Ex. 14; Defs' Ex. 61 at 2; Defs'. Ex. 84 at -618197, -618203–07.

[259] Am. Compl. ¶ 237; Defs.' Ex. 64 at -575.

[260] Am. Compl. ¶ 248; Defs.' Ex. 66 at -620851.

safety. It was not until April 2019—after the FAA grounded the 737 MAX fleet—that the Board built in time to address airplane safety.[261]

Defendants argue the Board "regularly discussed" safety as part of its strategic initiatives, pointing to slide decks that nod to "safety" as an "enduring value"[262] and as part of a "production system" that was simultaneously focused on "[a]ccelerating productivity."[263] They also point out that the Board was updated on the 737 MAX's development, production, and certification,[264] and that the Board inspected the plants where the 737 MAX was assembled, including on a June 2018 inspection of the Everett production site.[265] Defendants stress that the Board "oversaw the quality and safety of the 737 MAX program through monitoring the progress of the FAA's extensive certification review of the 737 MAX."[266]

But the invocations of safety Defendants highlight must be considered in the broader context Plaintiffs plead. The Board focused on the 737 MAX's production, development, and certification in order to assess production timelines and revenue

---

[261] Am. Compl. ¶ 79; Defs.' Ex. 75; Defs.' Ex. 77.

[262] Defs.' Ex. 16 at -11080, -13052.

[263] Defs.' Ex. 17 at -11645; *see also* Defs.' Ex. 20 at -13057 (including the tagline "[e]nsuring the safety, integrity and quality of Boeing products" in a test evaluation update).

[264] D.I. 146 at 19–22; Defs.' Ex. 8 at -11183; Defs.' Ex. 28; Defs.' Ex. 29; Defs.' Ex. 39 at -8133; Defs.' Ex. -8086; Defs.' Ex. 41 -8314; Defs.' Ex. 52 at -11403.

[265] Defs.' Ex. 26; Defs.' Ex. 27; Defs.' Ex. 28; Defs.' Ex. 29.

[266] D.I. 146 at 20.

expectations, and to strengthen the Company's relationships with FAA officials—not to consider customer safety.[267] The Board and management's passive invocations of quality and safety, and use of safety taglines, fall short of the rigorous oversight *Marchand* contemplates.

And under *Marchand*, minimal regulatory compliance and oversight do not equate to a *per se* indicator of a reasonable reporting system. "[T]he fact that [Boeing] nominally complied with F[A]A regulations does not imply that the *board* implemented a system to monitor [airplane] safety *at the board level*. Indeed, these types of routine regulatory requirements, although important, are not typically directed at the board."[268] The fact that Boeing's management was seeking minimal regulatory certification and periodically informing the Board of its progress in pursuit of production-based business objectives "does not rationally suggest that the board implemented a reporting system to monitor [airplane] safety or [Boeing's] operational performance," as "[t]he mundane reality that [Boeing] is in a highly regulated industry and complied with some of the applicable regulations does not foreclose any pleading-stage inference that the directors' lack of attentiveness rose

[267] Am. Compl. ¶¶ 127–28 (addressing board presentations containing taglines such as "*Performance, schedule, and cost certain . . . Stingy with a purpose*" and "*Transforming production system to support market demand*," and "Imperatives" such as "Break Cost Curve," "Faster to Market," and "Affordability Culture").

[268] *Marchand*, 212 A.3d at 823.

to the level of bad faith indifference required to state a *Caremark* claim."[269] As *Marchand* made plain, the fact that the company's product facially satisfies regulatory requirements does not mean that the board has fulfilled its oversight obligations to prevent corporate trauma.

iii. The Board had no regular process or protocols requiring management to apprise the Board of airplane safety; instead, the Board only received **ad hoc** *management reports that conveyed only favorable or strategic information.*

As alleged, the Board did not simply fail to assess safety itself; it also failed to expect or demand that management would deliver safety reports or summaries to the Board on a consistent and mandatory basis. The Amended Complaint's allegations and exhibits incorporated by reference show that the Board received intermittent, management-initiated communications that mentioned safety in name, but were not safety-centric and instead focused on the Company's production and revenue strategy. And when safety was mentioned to the Board, it did not press for further information, but rather passively accepted management's assurances and opinions.[270]

---

[269] *Id.*

[270] *See* Defs. Ex. 53; Defs.' Ex. 56; Defs.' Ex. 58; Defs.' Ex. 59; Defs.' Exs. 62–63; Defs.' Ex. 86; Am. Compl. ¶¶ 214, 224, 225, 227, 228.

For mission-critical safety, discretionary management reports that mention safety as part of the Company's overall operations are insufficient to support the inference that the Board expected and received regular reports on product safety.[271] Boeing's Board cannot leave "compliance with [airplane] safety mandates to management's discretion rather than implementing and then overseeing a more structured compliance system."[272] An effective safety monitoring system is what allows directors to believe that, unless issues or "red flags" make it to the board through that system, corporate officers and employees are exercising their delegated powers in the corporation's best interest.[273]

Here, the reports the Board received throughout the 737 MAX's development and FAA certification were high-level reports focused on the Company's operations and business strategy; the Board did not expect any safety content.[274] After the Lion Air Crash, management's communications to the Board demonstrate the lack of a Board process or protocol governing such communications.[275] None of

---

[271] *See Marchand*, 212 A.3d at 823–24.

[272] *Clovis*, 2019 WL 4850188, at *12 (describing *Marchand*).

[273] *See Forsythe v. ESC Fund Mgmt. Co. (U.S.)*, 2007 WL 2982247, at *7 (Del. Ch. Oct. 9, 2007).

[274] *See* Defs.' Ex. 40 at -8086; Defs.' Ex. 41.

[275] *See, e.g.*, Am. Compl. ¶ 91("In July 2018, Boeing's Test and Evaluation department voiced concerns to 'Boeing Executive Leadership' regarding the 'considerable pressure' the 737 MAX program faced over production schedules. The department's letter identifies the 'ero[sion of] safety margins' due to the declining average experience among senior production pilots. [Boeing's] Employee Relations Director . . . . forwarded the

Muilenburg's communications in the weeks following the Lion Air Crash were initiated by a Board request, either as a one-off or as part of a standing protocol. Muilenburg sent them at his discretion.[276] In the absence of a safety mandate, Muilenburg's self-directed communications to the Board focused on discrediting media reports faulting MCAS, and on blaming Lion Air repair shops and crew.

Muilenburg did not send any communication to the Board about the Lion Air Crash until November 5, 2018, roughly one week after it happened.[277] In that email, he disclosed that an airspeed indicator was damaged, but treated the Lion Air crash as a public relations problem and maintained to the Board that the "737 MAX fleet is safe."[278] Muilenburg contacted the Board again after the *WSJ* Article was printed: he gave lip service to the idea that "[t]he safety of our planes is our top priority," but claimed the references to withholding information "are categorically false," that existing flight crew procedures were adequate, and that the 737 MAX was safe.[279] Muilenburg's assurances to the Board that the 737 MAX was safe were based on unreliable information, as he emphasized the "rigorous test program" Boeing

---

communication to defendant Hyslop, Boeing's chief engineer, but . . . mischaracterized the letter as seeking mainly compensation and additional benefits, without flagging the safety concerns of overworked employees.").

[276] *See* Defs.' Ex. 53; Defs.' Ex. 56; Defs.' Ex. 57; Defs.' Ex. 58; Am. Compl. ¶¶ 206, 229.

[277] At argument, Boeing's counsel explained this was so because the crash occurred overseas and in the water. *See* Hr'g Tr. 27.

[278] Defs.' Ex. 55.

[279] Am. Compl. Ex. D.

endured "[t]o earn FAA certification."[280] His primary focus was the restoration of Boeing's public image.[281]

In the months that followed, Muilenburg's updates focused on Boeing's image and the accident's impact on the 737 MAX's production and delivery schedule, not product safety.[282] His monthly dashboard reports to the Board and regular updates on Company engineering initiatives addressed production and cost expectation and challenges, but not safety.[283] He repeatedly told the Board the 737 MAX was safe and blamed pilot and maintenance error.[284] Nothing indicates that the Board pressed him for more information about the cause of the accident or questioned management's conclusion.[285]

---

[280] *Id.*; *accord* Defs.' Ex. 57.

[281] Am. Compl. Ex. D; *accord* Defs.' Ex. 57.

[282] *See, e.g.*, Defs.' Ex. 56 (focusing on "our strong performance [a]s supported by our continued 737 recovery); Defs.' Ex. 58 (stating that Boeing "must allow [the investigation] to run its course," maintaining the "[b]ottom line" that "the 737 MAX is safe," and ultimately concluding with an update on "737 production" and touting that the Company completed "43 deliveries for October," "an all-time high for the month and a positive sign or production recovery plane and supplier management efforts are working"); Defs.' Ex. 60.

[283] *See* Defs.' Ex. 21; Defs.' Ex. 22 at -18838.

[284] *See, e.g.*, Am. Compl. ¶¶ 218, 225; Defs.' Ex. 58.

[285] While Muilenburg himself was Chairman of the Board at this time, Defendants have not attempted to impute his knowledge to the Board as a whole. *See* Am. Compl. ¶ 37.

Muilenburg's notes did not reference any Board-level directives for reporting or on investigating the Lion Air Crash.[286] Rather, they indicated that Boeing's management was taking charge while the Board remained a passive recipient of updates: management would "determine whether any action is required," and Muilenburg would "share additional details, if available, in [his] monthly update."[287] Those updates, too, were discretionary and not Board-ordered safety reports.

The Board's reliance on management-directed intermittent safety reporting continued after the Ethiopian Airline Crash. The Board passively accepted Muilenburg's assurances that Boeing's "teams are centered on our priorities, including safety, quality and stability,"[288] as an "ongoing" component of its "production operations";[289] and that public and regulatory backlash was driven solely by "public/political pressure, not by any new facts" about the 737 MAX's safety.[290] The Board did not press for more information. On March 12, Muilenburg emailed the Board about engagement with high federal executive branch officials to

[286] *See* Defs.' Ex. 57.

[287] *E.g.*, Defs.' Ex. 55.

[288] Defs.' Ex. 66 at -620851.

[289] *Id.*

[290] Defs.' Ex. 68.

keep the 737 MAX flying.[291] One outside director praised Muilenburg's "strong leadership."[292]

It was not until April 2019, the month following the Ethiopian Airline Crash, that Boeing's Vice President of BCA Engineering and BCA's Vice President of Safety, Security & Compliance presented to the Board. This was the first time that the Board or any of its committees heard a presentation from either member of management, "despite their roles leading engineering and safety, respectively, for Boeing's largest segment."[293]

The nature and content of management's *ad hoc* reports to the Board indicate that the Board had no regular process or protocols requiring management to apprise the Board of airplane safety.[294] Nothing in the Amended Complaint or documents

---

[291] *Id.*

[292] Am. Compl. ¶ 252.

[293] *Id.* ¶ 71.

[294] Hr'g Tr. 14–16 ("THE COURT: Where can I see that expectation and practice from the board's side rather than management coming forward and – you've pointed me to some examples of management coming forward to the board. Can you point me to any examples of where the board has expressed its expectation that management do so? MR. RABINOVITZ: I can't point you to a written protocol, Your Honor . . . [But] the fact that this practice existed is a meaningful indication of the protocol that did exist between management and the board. The board doesn't need to say so. The proof is in the pudding, as it were. . . . THE COURT: Just before you do that, just to put a bit of a finer point on it, the protocol that you're offering is manifested only when management chose to elevate issues to the board? MR. RABINOVITZ: This specific part, right. Elevating specific safety issues when management believed they warranted board attention. I cannot point to that in writing.").

submitted supports the inference that the Board requested those reports or expected those reports to contain safety information.[295]

Management's *ad hoc* reports were also one-sided at best and false at worst, conveying only favorable and optimistic safety updates and assurances that the quality of Boeing's aircraft would drive production and revenue. Management reported its unsupported conclusion that MCAS and the AOA sensor did not cause the crashes and that the 737 MAX remained airworthy and able to meet production goals. Management told the Board that "the function performed by MCAS" was referenced in the Flight Crew Operations Manual, and expressed frustration with public commentary.[296] Muilenburg also told the Board that Boeing was developing a "737 MAX software enhancement that, when implemented, will further improve system safety," and that "[d]espite recent media speculation," nothing had been decided about the "software update and its timing"—understating that "enhancement['s]" lifesaving importance.[297]

Because the Board did not have any formal procedures in place to monitor the safety of Boeing's airplanes, the Board was not privy to the truth about MCAS, AOA sensor vulnerabilities, or how those issues were handled in FAA certification and

---

[295] *See id*. 14–16, 19–21, 32, 47–48.

[296] Am. Compl. ¶ 224.

[297] *Id*. ¶ 234; Defs.' Ex. 63 at -13683.

pilot training.[298] It accepted Muilenburg's denials, deflections, and repeated insistence that the 737 MAX was safe, even after the press faulted MCAS and insufficient training for the Lion Air Crash.

The fact that management only communicated with the Board regarding safety on an *ad hoc* basis as necessary to further business strategy, and the fact that management only gave the board "certain favorable information" but not "important reports that presented a much different picture," indicate that the Board failed to implement a reasonable reporting system to monitor the safety of Boeing's airplanes.[299]

iv. Management saw red, or at least yellow, flags, but that information never reached the Board.

In *Marchand*, the Supreme Court agreed with the plaintiff that management's knowledge about growing safety issues in the company and failure to report those issues to the board was "further evidence that the board had no food safety reporting system in place."[300] Where management received reports that contained what could be considered red, or at least yellow, flags, and the board minutes of the relevant

---

[298] *See* Hr'g Tr. 32 ("MR. RABINOVITZ: I do not think there is anything in the record suggesting that the board was briefed on the MCAS at all before the – before the first 737 MAX accident.").

[299] *See Marchand*, 212 A.3d at 822.

[300] *Id*. at 817.

period revealed no evidence that these were disclosed to the board, it is reasonable to infer the absence of a reporting system.[301] Here, as in *Marchand*, Boeing management knew that the 737 MAX had numerous safety defects, but did not report those facts to the Board.

In the critical period leading up to the Lion Air Crash, Boeing management received formal complaints from employees who questioned the safety of the 737 MAX. Further, Boeing's Internal Safety Analysis found that if a pilot took more than ten seconds to identify and respond to the MCAS activation, the result would be catastrophic. Forkner made MCAS's vulnerability issues known within the Company. But before the Lion Air Crash, there is no evidence that management apprised the Board of the AOA disagree sensor's malfunctions or the probability of catastrophic failure.[302]

After the Lion Air Crash, Boeing started revising MCAS and, like the FAA, performed a risk assessment that concluded an unacceptably high risk of catastrophic failure. Boeing also pushed out the Manual Bulletin, and the FAA issued the

---

[301] *Id*. at 822.

[302] *See* Hr'g. Tr. 32 ("MR. RABINOVITZ: I do not think there is anything in the record suggesting that the board was briefed on the MCAS at all before the – before the first 737 MAX accident.").

Emergency Directive.[303] But management told the Board the 737 MAX was safe, and did not brief the Board on the risks of MCAS.

Thus, safety concerns known to management failed to make their way to the Board, supporting the conclusion that the Board failed to establish a reporting system.

v. In addition to the inferences drawn above, the pleading-stage record supports an explicit finding of scienter.

Plaintiffs have pled facts that allowing a reasonable inference that the directors breached their duties of oversight with scienter: not only did the Director Defendants act inconsistently with their fiduciary duties, but they also knew of their shortcomings.[304] In *Marchand*, the Delaware Supreme Court inferred scienter from the lack of any board committee focused on safety; any regular process or protocols requiring management to report on safety risks; any regular schedule for the board to address safety; any board minutes or documents suggesting that they regularly discussed safety; any evidence that red, or at least yellow, flags, were disclosed to the board; and any evidence that management conveyed both favorable and

[303] Am. Compl. ¶¶ 189–91.

[304] *See, e.g.*, *Horman*, 2017 WL 242571, at *7 (quoting *Massey*, 2011 WL 2176479, at *22).

unfavorable safety information to the board.[305] Those allegations support an inference of scienter here as well.

But no inference is needed: the difficult scienter element is directly met by the Board's own words. They confirm that directors knew the Board should have had structures in place to receive and consider safety information. Collins's March 15, 2019 email to Calhoun is exemplary. In the absence of Board meetings and discussions about safety before the crashes, Collins pitched that "we should devote the entire board meeting (other than required committee meetings and reports) to a review of quality within Boeing," because "[i]n addition to providing necessary information for the Board, this type of agenda would underscore the board's (and management's) unwavering commitment to quality and safety above all other performance criteria."[306] Collins's follow-up email on the "category of 'lessons learned'" reflected on his and Calhoun's time at Medtronic, where they "began each board meeting, executive committee meeting, and operating review with a review of product quality/safety—before any discussion of financial performance, market share/competitive activities, new product development timetables, and certainly stock price,"[307] so that "everyone in the corporation understood that nothing was

[305] *Marchand*, 212 A.3d at 822.

[306] Am. Compl. Ex. C.

[307] *Id.*

more important to the CEO and the board than quality/safety."[308] In response, Muilenburg "added Safety data to the Board lead-off briefing, and . . . monthly Board note too,"[309] and the Board held its first meetings to formally address airplane safety.

That the Board knowingly fell short is also evident in the Board's public crowing about taking specific actions to monitor safety that it did not actually perform. Calhoun hustled to "[p]osition the Boeing Board of Directors as an independent body that has exercised appropriate oversight."[310] He falsely touted that the Board was immediately contacted and met "very, very quickly" after the Lion Air Crash;[311] participated in evaluating the 737 MAX's safety risks; considered grounding the 737 MAX after the Lion Air Crash;[312] met within twenty-four hours of that crash to consider grounding; and recommended grounding.[313] Each of Calhoun's public representations was knowingly false.[314] They evidence that at least Calhoun knew what the Board should have been doing all along.

---

[308] *Id.*

[309] *Id.*

[310] Am. Compl. ¶ 263.

[311] *Id.* ¶¶ 268–69.

[312] *Id.* ¶ 271.

[313] *Id.* ¶¶ 274–75.

[314] *See, e.g.*, *id.* ¶¶ 271–76; Defs.' Ex. 69. As stated, Count I of the Amended Complaint categorizes the Board's public deception as a breach of fiduciary duty. Although the parties

* * * * *

Plaintiffs have met their "onerous pleading burden" under *Caremark* prong one, and are entitled to discovery to prove out that claim.[315] As espoused in *Marchand*, the Board has a rigorous oversight obligation where safety is mission critical, as the fallout from the Board's utter failure to try to satisfy this "bottom-line requirement"[316] can cause "material suffering," even short of death, "among customers, or to the public at large," and attendant reputational and financial harm to the company.[317] Plaintiffs allege a majority of the Director Defendants face liability under that theory, and have stated a claim.

b. Plaintiffs Have Stated A Post-Lion Air Claim Under *Caremark* Prong Two.

Plaintiffs also contend the Director Defendants face a substantial likelihood of liability under *Caremark* prong two because they ignored the Lion Air Crash and other red flags about the 737 MAX's safety before the Ethiopian Airlines Crash.[318] "To state a prong two *Caremark* claim, Plaintiff must plead particularized facts that the board knew of evidence of corporate misconduct—the proverbial red flag—yet

---

did not focus on that allegation in briefing or at argument, to the extent Plaintiffs pursue the Board's misrepresentations as an independent breach, the Motion is DENIED.

[315] *Marchand*, 212 A.3d at 824.

[316] *Id*. at 821.

[317] *Chou*, 2020 WL 5028065, at *1.

[318] By the time of the October 2018 Lion Air Crash, Stephenson and McNerney were no longer on the Board.

acted in bad faith by consciously disregarding its duty to address that misconduct."[319] Plaintiffs have done so here.

A classic prong two claim acknowledges the board had a reporting system, but alleges that system brought information to the board that the board then ignored.[320] In this case, Plaintiffs' prong two claim overlaps and coexists with their prong one claim; Plaintiffs assert the Board ignored red flags at the same time they utterly failed to establish a reporting system.[321]

I can appreciate the breadth of Plaintiffs' theory in view of the Board's pervasive failures under prong one and the scale of the tragedy that followed. Boeing's safety issues manifested in the Lion Air Crash—an accident the Board

---

[319] *Id*. at *17 (alterations and internal quotation marks omitted) (quoting *Reiter*, 2016 WL 6081823, at *8).

[320] *See, e.g.*, *Pettry on behalf of FedEx Corp. v. Smith*, 2021 WL 2644475, at *7–12 (Del. Ch. June 28, 2021) (reciting the *Caremark* prong two standard, and finding that the board did not ignore red flags that were elevated through the company's reporting system); *Clovis*, 2019 WL 4850188, at *13 (quoting *Marchand*, 212 A.2d at 821) ("*Caremark*'s second prong is implicated when it is alleged the company implemented an oversight system but the board failed to 'monitor it.'"); *cf. Chou*, 2020 WL 5028065, at *17–26 (concluding that the board consciously ignored red flags that were raised to the board where "Plaintiffs allege[d] that the Director Defendants face a substantial likelihood of liability under *both* prongs of *Caremark*").

[321] *See, e.g.*, *Chou*, 2020 WL 5028065, at *26 ("Because the Complaint survives under a 'prong two' theory, I need not decide whether the Director Defendants face a substantial likelihood of liability under 'prong one' of *Caremark*. I note, however, that the Davis Polk Report indicates that several years after acquiring Specialty, ABC had a woefully inadequate compliance system. While the implication of a 'prong one' claim is unnecessary to survive the Defendants' Motion, it nonetheless speaks to a lax approach (at best) to compliance at ABC.").

could not help but learn about, despite the lack of a Board-level monitoring system. Unlike many harms in the *Caremark* context, which include financial misconduct that the board can likely discover only through an internal system, the Board did not require an internal system to learn about the Lion Air Crash and the attendant MCAS failures.[322] The Lion Air Crash and its causes were widely reported in the media; those reports reached the Board; and the Board ignored them.[323]

But I need not decide today whether Plaintiffs' prong two theory is cognizable in view of my conclusion that the Board utterly failed under prong one. Defendants press that "the Board had extensive reporting systems and controls," including its Audit Committee, ERV, ethics and compliance reporting portals, internal audits group, and regular management and legal updates.[324] Assuming Defendants are correct, the Board nonetheless ignored the Lion Air Crash and the consequent revelations about the unsafe 737 MAX.

The Lion Air Crash was a red flag about MCAS that the Board should have heeded but instead ignored. The Board did not request any information about it from management, and did not receive any until November 5, 2018, over one week after it happened. In that communication, Muilenburg advanced management's position

---

[322] *See, e.g.*, Am. Compl. ¶¶ 195–98, 208–09; *id.* Ex. D; Defs.' Ex. 55; Hr'g Tr. 32.

[323] *See* Am. Compl. ¶¶ 195–98, 208–09; *id.* Ex. D; Defs.' Ex. 55.

[324] D.I. 146 at 38.

that the 737 MAX was safe, and the Board passively accepted that position. The November 12 *WSJ* Article circulated the theory that MCAS had serious engineering defects that were concealed from regulators and pilots, which required immediate investigation and remediation. The Board was aware of that article, but did not question management's contrary position. The Section 220 record does not reveal evidence of any director seeking or receiving additional written information about MCAS or the AOA sensor, Boeing's dealings with the FAA, how it had obtained FAA certification, the required amount of pilot training for the 737 MAX, or about airplane safety generally.[325]

When the Board finally convened to address the Lion Air Crash, the call was optional. The full Board did not anchor the tragedy as an agenda item until it met for its regularly scheduled Board meeting in December 2018, and its focus at that meeting was on the continued production of the 737 MAX, rather than MCAS, potential remedial steps, or safety generally.[326] And when the Board eventually considered whether it should investigate the causes of the Lion Air Crash, at the February 2019 Board meeting, the Board formally resolved to "delay any

[325] *See In re Tyson Foods, Inc.*, 919 A.2d 563, 578 (Del. Ch. 2007) ("[I]t is more reasonable to infer that exculpatory documents would be provided than to believe the opposite: that such documents existed and yet were inexplicably withheld.").

[326] Am. Compl. ¶ 231–32; Defs.' Ex. 84 at -618203.

investigation until the conclusion of the regulatory investigations or until such time as the Board determines that an internal investigation would be appropriate."[327]

Electing to follow management's steady misrepresentations that the 737 MAX fleet was safe and airworthy, the Board treated the crash as an "anomaly," a public relations problem, and a litigation risk,[328] rather than investigating the safety of the aircraft and the adequacy of the certification process. The Board's declination to test the modicum of information it received and seek the truth of the 737 MAX's safety, despite reported information calling it into question, do not indicate a mere "failed attempt" to address a red flag.[329] As alleged and supported by the Section 220 record, the Board was aware or should have been aware that its response to the Lion Air Crash fell short.[330]

---

[327] Am. Compl. ¶ 238; Pls.' Ex. 4.

[328] Am. Compl. ¶ 271.

[329] *Cf. Richardson v. Clark*, 2020 WL 7861335, at *11 (Del. Ch. Dec. 31, 2020); *In re Qualcomm FCPA S'holder Deriv. Litig.*, 2017 WL 2608723, at *4 (Del. Ch. June 16, 2017).

[330] *See* Am. Compl. Ex. C (addressing "lessons learned' and the Board's need to begin addressing safety in a formal setting); *Rich ex rel. Fuqi Int'l, Inc. v. Yu Kwai Chong*, 66 A.3d 963, 983–84 (Del. Ch. 2013) (finding scienter where company's directors "knew that there were material weaknesses in [the company's] internal controls"); *cf. In re GoPro, Inc.*, 2020 WL 2036602, at *13 (Del. Ch. Apr. 28, 2020) (declining to find that Plaintiffs offered "well-pled facts supporting an inference that a majority of the Demand Board personally *knew* about Karma's defect, could meaningfully address the issue at the Board level and yet elected to do nothing").

2. Plaintiffs Have Not Pled Particularized Facts Demonstrating The Director Defendants Face A Substantial Likelihood Of Liability With Respect To Muilenburg's Retirement And Compensation.

Plaintiffs also allege that the Director Defendants consciously breached their fiduciary duties by allowing Muilenburg to receive unvested equity-based compensation in a quiet retirement, despite knowing that he misled the FAA and the Board, and failed in his response to the Lion Air and Ethiopian Airlines Crashes. Plaintiffs couch this claim as one for waste or, in the alternative, bad faith.[331] But Plaintiffs have not alleged particularized facts sufficient to demonstrate that the Director Defendants face a substantial likelihood of liability under these rigorous standards.[332]

Plaintiffs do not meaningfully challenge the independence and disinterestedness of the Board as to the terms of Muilenburg's departure. Plaintiffs theorize the Board bought Muilenburg's silence because he knew the depth of the Board's ignorance about the 737 MAX. Plaintiffs contend that the Board acted out of self-interest by allowing Muilenburg to retire and claim his unvested equity

---

[331] *See* D.I. 155 at 56–61.

[332] This is true whether the Board's decision to terminate Muilenburg is considered under *Aronson* or *Rales*. *See Zuckerberg*, 250 A.3d at 877–90; *see also* D.I. 146 at 58 ("Whether the Board's decision to terminate Muilenburg is considered under *Aronson* or *Rales*, . . .Plaintiffs fail to establish demand futility."); *id.* at 60 (assessing Plaintiffs' claims under *Rales*); D.I. 155 at 38 (citing and applying *Rales*).

because "Muilenburg could have accused the Board members of unfairly scapegoating him for doing what the Board wanted."[333] They argue "[t]he Board's pronounced lack of safety oversight incentivized the Board members not to make an enemy of Muilenburg at a time of public clamor over whether the Board bore any culpability for the mass fatalities and resulting financial catastrophe at Boeing."[334] But Plaintiffs do not plead particularized facts supporting their theory that "[p]aying Muilenburg encouraged his silence about his interactions with the Board."[335] Nothing in the Section 220 production gives rise to the reasonable inference that Muilenburg intended to retaliate against the Board by placing the blame at its feet. This theory is conclusory.

Further, Plaintiffs have not pled particularized facts giving rise to the inference that the Board would face a substantial likelihood of liability under waste or bad faith theories. "[T]he standard for waste is a very high one that is difficult to meet,"[336] and "to prevail on a waste claim the plaintiff must overcome the general presumption of good faith by showing that the board's decision was so egregious or irrational that it could not have been based on a valid assessment of the corporation's

---

[333] D.I. 155 at 59.

[334] *Id*. at 60.

[335] *Id*.

[336] *In re Walt Disney Co. Deriv. Litig.*, 907 A.2d 693, 759 (Del. Ch. 2005).

best interests."[337] "[T]o excuse demand on grounds of waste the Complaint must allege particularized facts that lead to a reasonable inference that the director defendants authorized 'an exchange that is so one sided that no business person of ordinary, sound judgment could conclude that the corporation has received adequate consideration.'"[338] The burden to establish a claim for bad faith is similarly stringent. A finding of bad faith in the fiduciary context is rare.[339] "Absent direct evidence of an improper intent, a plaintiff must point to a decision that lacked any rationally conceivable basis . . . to survive a motion to dismiss."[340]

The Amended Complaint and the Section 220 record do not support such claims here, as it is reasonable to infer that the Board was validly exercising its business judgment when it decided to allow Muilenburg to retire with compensation. At that time, Boeing was facing substantial backlash and had spent millions of

---

[337] *Citigroup*, 964 A.2d at 136 (alterations and internal quotation marks omitted).

[338] *Id.*

[339] *See In re Saba Software, Inc. S'holder Litig.*, 2017 WL 1201108, at *20 (Del. Ch. Mar. 31, 2017) (citing *In re Chelsea Therapeutics Int'l Ltd. S'holders Litig.*, 2016 WL 3044721, at *1 (Del. Ch. May 20, 2016)). That said, I acknowledge the bulk of this opinion concludes the Director Defendants face liability for bad faith dereliction of their oversight duties.

[340] *In re Essendant, Inc. S'holder Litig.*, 2019 WL 7290944, at *14 (Del. Ch. Dec. 30, 2019) (alteration and internal quotation marks omitted) (quoting *Chen v. Howard-Anderson*, 87 A.3d 648, 684 (Del. Ch. 2014)); *see also Chelsea Therapeutics*, 2016 WL 3044721, at *1 (stating that in cases where "there is no indication of conflicted interests or lack of independence on the part of the directors," a finding of bad faith should be reserved for situations where "the nature of [the directors'] action can in no way be understood as in the corporate interest: *res ipsa loquitur*").

dollars addressing the 737 MAX corporate trauma. Even accepting as true that the Board allowed Muilenburg to go quietly and with full pockets to avoid further public criticism, it is reasonable to infer that doing so was in furtherance of the legitimate business objective of avoiding further reputational and financial harm to the Company.[341] Accordingly, Plaintiffs have failed to allege particularized facts that the decision to forego Muilenburg's termination for cause "was otherwise the product of a valid exercise of business judgment."[342] The Motion is therefore granted as to Plaintiffs' Muilenburg compensation claims.

B. The Motion Is Granted As To Count II's Claim Against The Officer Defendants.

Defendants have also moved to dismiss all claims against the Officer Defendants under Rules 23.1 and 12(b)(6). Defendants argue that Plaintiffs do not plead with particularity facts establishing that demand is excused for Count II of their Complaint, alleging breach of fiduciary duty by Boeing's officers.[343]

---

[341] *See Shabbouei v. Potdevin*, 2020 WL 1609177, at *12 (Del. Ch. Apr. 2, 2020) ("[T]he Board was operating well-within the bounds of proper business judgment when it decided to settle with [the former CEO] rather than fire him 'for cause,' a decision that could have embroiled the Company in an embarrassing legal battle with its former CEO."); *Seinfeld v. Slager*, 2012 WL 2501105, at *6 (Del. Ch. June 29, 2012) ("Other factors may also properly influence the board, including ensuring a smooth and harmonious transfer of power, securing a good relationship with the retiring employee, preventing future embarrassing disclosure and lawsuits, and so on.").

[342] *Aronson*, 473 A.2d at 814.

[343] D.I. 146 at 60.

Defendants further argue that Delaware does not recognize *Caremark* claims against officers, and that Plaintiffs have failed to allege that the Officer Defendants breached their duty of care.[344]

In briefing, Plaintiffs did not address Defendants' demand futility arguments as to Count II.[345] Instead, Plaintiffs' theory under Rule 23.1 presumably turns on the assumption that the Officer Defendants can face *Caremark* liability, and that therefore demand was futile as to all Defendants facing the same claim. But Plaintiffs have not pled this with the requisite particularity, nor have they argued that any of the Director Defendants are beholden to or dominated by the Boeing officers such that they would be unable to assess Count II regardless of the theory of liability.[346] Indeed, the Amended Complaint's demand futility allegations do not address the Officer Defendants, asserting only that "a majority of the members of the Board have faced a substantial likelihood of liability for failing to make any good faith effort to implement and oversee a board-level system to monitor and report on

---

[344] *See id*. at 61–62.

[345] *See generally* D.I. 155; D.I. 159 at 33.

[346] *E.g.*, *In re MetLife, Inc. Deriv. Litig.*, 2020 WL 4746635, at *13 n.186 (Del. Ch. Aug. 17, 2020) (pointing out that plaintiffs did not argue that any board members were beholden to management so as to disable them from evaluating the claims); *Rales*, 634 A.2d at 936.

safety."[347] Accordingly, Count II is dismissed pursuant to Rule 23.1, and therefore I need not address Defendants' arguments under Rule 12(b)(6).

III. CONCLUSION

The Motion is **GRANTED** in part and **DENIED** in part. The parties shall submit an implementing order with twenty days of this decision.

[347] Am. Compl. ¶ 299.

Health Lawyers' Public Information Series

THE HEALTH CARE DIRECTOR'S COMPLIANCE DUTIES: A Continued Focus of Attention and Enforcement

A Joint Publication from the Office of the Inspector General, U.S. Department of Health and Human Services and the American Health Lawyers Association

AMERICAN HEALTH LAWYERS ASSOCIATION

"...to serve as a public resource on selected healthcare legal issues"
—From the Mission Statement of the American Health Lawyers Association

About the Organizations

The Health Care Director's Compliance Duties: A Continued Focus of Attention and Enforcement is a compilation of three corporate compliance resources, originally issued in 2003, 2004, and 2007. Developed in collaboration between the American Health Lawyers Association (AHLA) and the Office of the Inspector General (OIG) of the United States Department of Health and Human Services (HHS), AHLA's Corporate Responsibility Series can assist directors of healthcare organizations carry out their oversight responsibilities.

The AHLA is the nation's largest, nonpartisan, 501(c)(3) educational organization devoted to legal issues in the healthcare field with more than 10,000 members. The OIG is the independent and objective oversight unit of HHS, with a mission of promoting economy, efficiency, and effectiveness in the department's programs through the elimination of waste, abuse, and fraud.

Reissuance of the now consolidated corporate compliance guidebooks was made possible by the generous support of The Governance Institute. www.GovernanceInstitute.com

Contributing Authors

Jane Reister Conard, Senior Counsel, Intermountain Healthcare, Inc.
Douglas A. Hastings, Epstein Becker Green
Michael C. Hemsley, General Counsel & Vice President Corporate Compliance, Catholic Health East
Lewis Morris, Chief Counsel to the Inspector General, Office of Inspector General, U.S. Department of Health & Human Services
Michael W. Peregrine, McDermott Will & Emery

© Copyright 2010, 2011
American Health Lawyers Association
All websites updated as of August 29, 2011.

This publication can be downloaded for free at www.healthlawyers.org/ComplianceDuties. Other resources in AHLA's Public Information Series are available at www.healthlawyers.org/PublicInterest.

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without the express, written permission of the publisher. Provided, however, that this publication may be reproduced in part or in whole without permission from the publisher for non-commercial educational purposes designed to improve health in communities and increase access to healthcare or improve the quality or maintain the cost of healthcare services. Any such community benefit distribution must be without charge to recipients and must include an attribution to American Health Lawyers Association as follows: "Copyright © 2010 by the American Health Lawyers Association and reproduced for the benefit of and to promote the health of the community served by the distributing organization."

1620 Eye Street, NW, 6th Floor
Washington, DC 20006-4010
Telephone: (202) 833-1100
www.healthlawyers.org

This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is provided with the understanding that the publisher is not engaged in rendering legal or other professional services. If legal advice or other expert assistance is required, the services of a competent professional person should be sought.
— from a declaration of the American Bar Association

The Health Care Director's Compliance Duties: A Continued Focus of Attention and Enforcement

Foreword 1

Synopsis 2

Corporate Responsibility and Corporate Compliance

I. Introduction 4
- A. Fiduciary Responsibilities 4
- B. Purpose of this Document 4

II. Duty of Care 5

III. The Unique Challenges of Health Care Organization Directors 6

IV. The Development of Compliance Programs 7

V. Suggested Questions for Directors 7
- A. Structural Questions 7
- B. Operational Questions 8
  - 1) Code of Conduct 9
  - 2) Policies and Procedures 9
  - 3) Compliance Infrastructure 9
  - 4) Measures to Prevent Violations 9
  - 5) Measures to Respond to Violations 10

VI. Conclusion 11

An Integrated Approach to Corporate Compliance

I. Introduction 12

II. The Role of General Counsel 13

III. An Integrated Response to Corporate Compliance 14

IV. Considerations for Health Care Boards 15

V. Summary Considerations 18
- A. Where the General Counsel Serves as the Chief Compliance Officer 18
- B. Where the Chief Compliance Officer is Separate from the General Counsel, but reports to the General Counsel 19
- C. Where the Compliance Officer is Separate from and Does Not Report to the General Counsel 19

VI. Conclusion 19

Appendix A – Survey Results, Conducted by the American Health Layers Association and Health Care Compliance Association 20

Corporate Responsibility and Health Care Quality

I. Introduction 26

II. Board Fiduciary Duty and Quality in the Health Care Setting 26
- A. Duty of Care 27
- B. Duty of Obedience to Corporate Purpose and Mission 28
- C. Summary 28

III. Defining Quality of Care and the Critical Need to Implement Quality Initiatives 29

IV. The Government's Role in Enforcing Health Care Quality 31

V. Health Care Board Fiduciary Duty and Quality 32

VI. Suggested Questions for Directors 33

VII. Conclusion 36

Since the initial publication of the three corporate responsibility resource guides by the American Health Lawyers Association (AHLA) and the Office of the Inspector General (OIG), U.S. Department of Health and Human Services (HHS), interest in the fiduciary duty of health care boards of directors, as it relates to compliance and quality, has continued to increase. Quality, cost efficiency, waste, and fraud are issues that are even more meaningful in light of the current health care reform debate.

In a recent survey[1] of published articles on governing board functions and responsibilities, the findings showed a very large increase in such articles published this decade. In the early 2000s, however, only a small minority of these related to quality and safety. By the late 2000s, nearly half related to quality and safety.

We note just a few specific examples of recent interest in the role of health care boards and quality of care: The Joint Commission, in 2007, published *Getting the Board on Board: What Your Board Needs to Know about Quality and Patient Safety*; the Institute for Healthcare Improvement, in 2006, published a white paper entitled *Leadership Guide to Patient Safety*; and the National Quality Forum, in 2004, published *Hospital Governing Boards and Quality of Care: A Call to Responsibility*.

The three articles in this AHLA-OIG Corporate Responsibilities Series now being reissued by The Governance Institute progressed in a similar direction—from a focus on defining the board's duty of care in the post-Sarbanes-Oxley and health care regulatory compliance context through a careful look at the roles of the general counsel and the chief compliance officer, to a specific look at corporate responsibility and health care quality.

Meanwhile, developments in corporate governance, fiduciary liability, non-profit organization oversight, and related areas continue to influence fiduciary duty in the health care setting. Case law continues to address standards of director conduct.[2] The IRS has stepped up its activities in the non-profit arena, both with the release of its more detailed Form 990 and further guidance on corporate governance. The economic crisis of 2008–2009 has brought renewed scrutiny of boards of directors' actions, including those of non-profit boards.[3]

State and federal enforcement agencies also are demonstrating a growing recognition of the role of health care boards in promoting quality of care and ensuring compliance with federal health care program rules. In a number of cases involving the provision of substandard care to Medicare and Medicaid patients, the responsible medical professional and the hospital have been held responsible for the failure to provide quality care. In a number of recent fraud settlements, the OIG has imposed corporate integrity agreements that require boards to provide heightened scrutiny of their institutions' compliance systems and to take responsibility for the effectiveness of internal controls. The New York State Office of Medicaid Inspector General also has a specific focus on compliance oversight obligations of governing boards and stated its intention to pursue enforcement actions in the appropriate cases.

The ongoing efforts to reform the nation's health care system also implicate the boards of health care institutions. As part of the movement to improve outcomes and reduce health care costs, Medicare and Medicaid are beginning to link hospital payments to the quality of care. In addition to financially rewarding hospitals that improve care, Medicare and some other public and private insurers also are starting to refuse payment for preventable errors. As the link between payment and quality of care grows, boards will need to be involved in the oversight of the care provided by their health care institutions.

In light of these developments, the three resource guides in this AHLA-OIG Corporate Responsibility Series are increasingly relevant for boards of health care organizations. We are grateful to The Governance Institute for its support and assistance in making this information available.

---

1 *See* William J. Oetgen, MD, MBA, *The Governing Board's Quality Agenda, An Overview*, Prescriptions for Excellence in Healthcare, Jefferson School of Population Health and Lilly USA, LLC, Issue 5, Summer 2009.

2 *See* Lyondell Chemical Co. v. Ryan, C.A. No. 401, 2008 (Del. March 25, 2009) and In re Citigroup Inc. Shareholder Derivative Litigation, 964 A.2d. 106 (Del. Ch. 2009).

3 *See Lehman Board Faulted for Excessive Pay, Poor Governance Practices in Face of Crisis*, BNA's Corporate Accountability Reporter, Vol. 6, No. 40, October 10, 2008, and Carrie Coolidge, *Blumenthal May Investigate Charities Ripped Off by Madoff*, Forbes.com, December 22, 2008.

The AHLA-OIG Corporate Responsibility Series (Series) consists of three corporate compliance guidance resources:

- *Corporate Responsibility and Corporate Compliance* (2003)
- *An Integrated Approach to Corporate Compliance* (2004)
- *Corporate Responsibility and Health Care Quality* (2007)

Individually and collectively, the components of this Series were intended as an educational resource to assist governing board members of health care organizations to more responsibly carry out their compliance plan oversight obligations under applicable law.

Given the increasing emphasis on corporate compliance from legislative, regulatory, and public policy perspectives, the need to provide board-level compliance guidance is greater than ever. For these reasons, the Series is being reissued, with the gracious assistance of The Governance Institute. The following is an "executive briefing" synopsis of each of the three components of the Series.

Corporate Responsibility and Corporate Compliance

☑ **Theme:** The expansion of health care regulatory enforcement and compliance activities and heightened attention being given to the responsibilities of health care directors are critically important to all health care organizations. It is thus appropriate to evaluate the health care board's unique fiduciary duty of compliance plan oversight and how that duty may be satisfied.

☑ **Key Points:**

- The duty of compliance plan oversight arises from the director's fundamental fiduciary duty of care.
- Specifically, "[A] director's obligations include a duty to attempt in good faith to assure that a corporate information and reporting system, which the board concludes is adequate, exists, and that failure to do so under some circumstances, may, in theory at least, render a director liable for losses caused by non-compliance with applicable legal standards." This is the so-called *Caremark* standard.[4]
- The circumstances of each organization differ and application of the duty of care and consequent reasonable inquiry will need to be tailored to each specific set of facts and circumstances.

☑ **Practical Applications:** While the opinion in *Caremark* established a board's duty to oversee a compliance program, it did not enumerate a specific methodology for doing so. This particular compliance resource is designed to assist health care directors in exercising that responsibility by offering a series of suggested questions for directors. Several "structural" questions explore the board's understanding of the scope of the organization's compliance program. The remaining questions are directed to the operations of the compliance program and may facilitate the board's understanding of its compliance program.

☑ **Why Still Relevant:** Regulators and other third parties continue to evaluate the board's exercise of its compliance plan oversight duties. For example, the New York State Medicaid Inspector General has made it clear by regulation that directors may be held accountable for ineffective oversight that contributes to compliance violations. Further, a series of decisions of the influential Delaware courts continue to apply the framework of the *Caremark* standard.

An Integrated Approach to Corporate Compliance

☑ **Theme:** The health care entity governing board plays an important role in reconciling differing views (*e.g.*, legislative, OIG, American Bar Association) regarding the proper role of the general counsel in health care compliance. The governing board should monitor the roles of the general counsel and the chief compliance officer in supporting the board's compliance oversight responsibilities.

☑ **Key Points:**

- Recent developments in the corporate and securities world have refocused attention on effective corporate governance and the role of the general counsel in promoting ethical conduct and compliance with the law.
- Consideration of the role of the general counsel in overseeing compliance programs has been ongoing.
- The OIG has historically perceived some risk where an otherwise independent compliance function is subordinate to the general counsel or financial officer.

4 *In re* Caremark International Inc. Derivative Legislation, 698 A.2d 959 (Del. Cn. 1996).

- The Code of Professional Responsibility in many states requires lawyers to report "up the ladder" violations of the law by officers, employees, or agents.
- The American Bar Association has taken the view that the general counsel should have primary responsibility for assuring the implementation of an effective legal compliance system under the board's oversight.
- A board member overseeing the compliance function should understand how the organization is addressing the issue of the role of the general counsel and chief compliance officer in the implementation of the organization's compliance plan.

☑ **Practical Applications:** This particular compliance resource includes a series of suggested questions/areas of inquiry that directors should pursue to ensure that (a) the board understands the role of the general counsel and the chief compliance officer in supporting the organization's corporate compliance program, and (b) appropriate processes are in place to assure the board that it receives appropriate information and candid assessments arising out of the compliance program in a timely manner. These suggested questions and related commentary recognize that boards may consider a variety of approaches in addressing these issues.

☑ **Why Still Relevant:** The interplay between the general counsel and the chief compliance officer remains of critical importance, especially as it relates to the board's ability to receive reports on compliance in a coordinated, comprehensive manner. Further, as recent Corporate Integrity Agreements have noted, the OIG continues to believe that compliance "checks and balances" are more effectively maintained when the compliance function is separated from management functions (*e.g.*, the general counsel).

Corporate Responsibility and Health Care Quality

☑ **Theme:** With a new era of focus on quality and patient safety rapidly emerging, oversight of quality is becoming more clearly recognized as a core fiduciary responsibility of health care organization directors. Boards have distinct compliance-related responsibilities in this area because quality of care is perceived as an enforcement priority for health care regulators.

☑ **Key Points:**

- Director obligations to monitor organizational quality of care arise from three particular bases: 1) the basic duty of care and the director's obligation to oversee day-to-day corporate operations; 2) the related duty to oversee the compliance program; and 3) the duty of obedience to corporate purpose/mission (*e.g.*, conduct of the institution as a hospital).
- These duties are in addition to traditional board obligations with respect to supervising medical staff credentialing decisions.
- Many new financial relationships address quality of care issues, *e.g.*, pay-for-performance programs, gainsharing, and outcomes management arrangements, among others.
- Government enforcement authorities are increasingly focusing on the quality of care provided to beneficiaries of federal and state health care programs and the organization's related legal liability profile.

☑ **Practical Applications:** This particular compliance resource seeks to help the health entity board as it develops an understanding of relevant quality and patient safety issues, and focuses on performance goals that help the organization provide the best quality and most efficient care. Accordingly, this resource includes a series of suggested questions that may be helpful as the board examines the scope and operation of the organization's quality and safety initiatives.

☑ **Why Still Relevant:** Health care quality and patient safety issues are at the forefront of multiple health care reform initiatives at both the federal and state level. Amendments to the False Claims Act increase the potential for substantial quality of care-based and similar enforcement actions related to quality of care concerns. Recent regulatory initiatives by the New York State Medicaid Inspector General demonstrate how quality of care oversight can be interpreted as a component part of an "effective" corporate compliance plan for a health care provider.

I. Introduction

As corporate responsibility issues fill the headlines, corporate directors are coming under greater scrutiny. The Sarbanes-Oxley Act, state legislation, agency pronouncements, court cases, and scholarly writings offer a myriad of rules, regulations, prohibitions, and interpretations in this area. While all Boards of Directors must address these issues, directors of health care organizations also have important responsibilities that need to be met relating to corporate compliance requirements unique to the health care industry. The expansion of health care regulatory enforcement and compliance activities and the heightened attention being given to the responsibilities of corporate directors are critically important to all health care organizations. In this context, enhanced oversight of corporate compliance programs is widely viewed as consistent with and essential to ongoing federal and state corporate responsibility initiatives.

Our complex health care system needs dedicated and knowledgeable directors at the helm of both for-profit and non-profit corporations. This educational resource, co-sponsored by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), and the American Health Lawyers Association (AHLA), the leading health law educational organization, seeks to assist directors of health care organizations in carrying out their important oversight responsibilities in the current challenging health care environment. Improving the knowledge base and effectiveness of those serving on health care organization boards will help to achieve the important goal of continuously improving the U.S. health care system.

A. Fiduciary Responsibilites

The fiduciary duties of directors reflect the expectation of corporate stakeholders regarding oversight of corporate affairs. The basic fiduciary duty of care principle, which requires a director to act in good faith with the care an ordinarily prudent person would exercise under similar circumstances, is being tested in the current corporate climate. Personal liability for directors, including removal, civil damages, and tax liability, as well as damage to reputation, appears not so far from reality as once widely believed. Accordingly, a basic understanding of the director's fiduciary obligations and how the duty of care may be exercised in overseeing the company's compliance systems has become essential.

Embedded within the duty of care is the concept of reasonable inquiry. In other words, directors should make inquiries to management to obtain information necessary to satisfy their duty of care. Although in the *Caremark* case, also discussed later in this educational resource, the court found that the *Caremark* board did not breach its fiduciary duty, the court's opinion also stated the following: "[A] director's obligation includes a duty to attempt in good faith to assure that a corporate information and reporting system, which the Board concludes is adequate, exists, and that failure to do so under some circumstances, may, in theory at least, render a director liable for losses caused by non-compliance with applicable legal standards." Clearly, the organization may be at risk and directors, under extreme circumstances, also may be at risk if they fail to reasonably oversee the organization's compliance program or act as mere passive recipients of information.

On the other hand, courts traditionally have been loath to second-guess Boards of Directors that have followed a careful and thoughtful process in their deliberations, even where ultimate outcomes for the corporation have been negative. Similarly, courts have consistently upheld the distinction between the duties of Boards of Directors and the duties of management. The responsibility of directors is to provide oversight, not manage day-to-day affairs. It is the process the Board follows in establishing that it had access to sufficient information and that it has asked appropriate questions that is most critical to meeting its duty of care.

B. Purpose of this Document

This educational resource is designed to help health care organization directors ask knowledgeable and appropriate questions related to health care corporate compliance. These questions are not intended to set forth any specific standard of care. Rather, this resource will help corporate directors to establish, and affirmatively demonstrate, that they have followed a reasonable compliance oversight process.

Of course, the circumstances of each organization differ and application of the duty of care and consequent reasonable inquiry will need to be tailored to each specific set of facts and circumstances. However, compliance with the fraud and abuse laws and other federal and state regulatory laws applicable to health care organizations is essential for the lawful behavior and corporate success of such organizations. While these laws can be complex, effective compliance is an asset for

both the organization and the health care delivery system. It is hoped that this educational resource is useful to health care organization directors in exercising their oversight responsibilities and supports their ongoing efforts to promote effective corporate compliance.

II. Duty of Care

Of the principal fiduciary obligations/duties owed by directors to their corporations, the one duty specifically implicated by corporate compliance programs is the *duty of care.*[1]

As the name implies, the duty of care refers to the obligation of corporate directors to exercise the proper amount of care in their decision-making process. State statutes that create the duty of care and court cases that interpret it usually are identical for both for-profit and non-profit corporations.

In most states, duty of care involves determining whether the directors acted (1) in "good faith," (2) with that level of care that an ordinarily prudent person would exercise in like circumstances, and (3) in a manner that they reasonably believe is in the best interest of the corporation. In analyzing whether directors have complied with this duty, it is necessary to address each of these elements separately.

The "good faith" analysis usually focuses upon whether the matter or transaction at hand involves any improper financial benefit to an individual, and/or whether any intent exists to take advantage of the corporation (a corollary to the duty of loyalty). The "reasonable inquiry" test asks whether the directors conducted the appropriate level of due diligence to allow them to make an informed decision. In other words, directors must be aware of what is going on about them in the corporate business and must, in appropriate circumstances, make such reasonable inquiry as would an ordinarily prudent person under similar circumstances. Finally, directors are obligated to act in a manner that they reasonably believe to be in the best interests of the corporation. This normally relates to the directors' state of mind with respect to the issues at hand.

In considering directors' fiduciary obligations, it is important to recognize that the appropriate standard of care is not "perfection." Directors are not required to know everything about a topic they are asked to consider. They may, where justified, rely on the advice of management and outside advisors.

Furthermore, many courts apply the "business judgment rule" to determine whether a director's duty of care has been met with respect to corporate decisions. The rule provides, in essence, that a director will not be held liable for a decision made in good faith, where the director is disinterested, reasonably informed under the circumstances, and rationally believes the decision to be in the best interest of the corporation.

Director obligations with respect to the duty of care arise in two distinct contexts:

- The *Decision-Making Function*: The application of duty of care principles to a specific decision or a particular board action, and
- The *Oversight Function*: The application of duty of care principles with respect to the general activity of the board in overseeing the day-to-day business operations of the corporation, *i.e., the exercise of* reasonable care to assure that corporate executives carry out their management responsibilities and comply with the law.

Directors' obligations with respect to corporate compliance programs arise within the context of that oversight function. The leading case in this area, viewed as applicable to all health care organizations, provides that a director has two principal obligations with respect to the oversight function. A director has a duty to attempt in good faith to assure that (1) a corporate information and reporting system exists, and (2) this reporting system is adequate to assure the board that appropriate information as to compliance with applicable laws will come to its attention in a timely manner as a matter of ordinary operations.[2] In *Caremark*, the court addressed the circumstances in which corporate directors may be held liable for breach of the duty of care by failing to adequately supervise corporate employees whose misconduct caused the corporation to violate the law.

In its opinion, the *Caremark* court observed that the level of detail that is appropriate for such an information system is a matter of business judgment. The court also acknowledged that no

1 The other two core fiduciary duty principals are the duty of loyalty and the duty of obedience to purpose.

2 *In re Caremark International Inc. Derivative Litigation,* 698 A.2d 959 (Del. Ch. 1996). A shareholder sued the Board of Directors of Caremark for breach of the fiduciary duty of care. The lawsuit followed a multi-million dollar civil settlement and criminal plea relating to the payment of kickbacks to physicians and improper billing to federal health care programs.

rationally designed information and reporting system will remove the possibility that the corporation will violate applicable laws or otherwise fail to identify corporate acts potentially inconsistent with relevant law.

Under these circumstances, a director's failure to reasonably oversee the implementation of a compliance program may put the organization at risk and, under extraordinary circumstances, expose individual directors to personal liability for losses caused by the corporate non-compliance.[3] Of course, crucial to the oversight function is the fundamental principle that a director is entitled to rely, in good faith, on officers and employees as well as corporate professional experts/advisors in whom the director believes such confidence is merited. A director, however, may be viewed as not acting in good faith if she is aware of facts suggesting that such reliance is unwarranted.

In addition, the duty of care test involving reasonable inquiry has not been interpreted to require the director to exercise "proactive vigilance" or to "ferret out" corporate wrongdoing absent a particular warning or a "red flag." Rather, the duty to make reasonable inquiry increases when "suspicions are aroused or *should be aroused*"—that is, when the director is presented with extraordinary facts or circumstances of a material nature (*e.g.*, indications of financial improprieties, self-dealing, or fraud), or a major governmental investigation. Absent the presence of suspicious conduct or events, directors are entitled to rely on the senior leadership team in the performance of its duties. Directors are not otherwise obligated to anticipate future problems of the corporation.

Thus, in exercising her duty of care, the director is obligated to exercise general supervision and control with respect to corporate officers. However, once presented (through the compliance program or otherwise) with information that causes (or should cause) concerns to be aroused, the director is then obligated to make further inquiry until such time as her concerns are satisfactorily addressed and favorably resolved. Thus, while the corporate director is not expected to serve as a compliance officer, she is expected to oversee senior management's operation of the compliance program.

III. The Unique Challenges of Health Care Organization Directors

The health care industry operates in a heavily regulated environment with a variety of identifiable risk areas. An effective compliance program helps mitigate those risks. In addition to the challenges associated with patient care, health care providers are subject to voluminous and sometimes complex sets of rules governing the coverage and reimbursement of medical services. Because federal and state-sponsored health care programs play such a significant role in paying for health care, material non-compliance with these rules can present substantial risks to the health care provider. In addition to recoupment of improper payments, the Medicare, Medicaid and other government health care programs can impose a range of sanctions against health care businesses that engage in fraudulent practices.

Particularly given the current "corporate responsibility" environment, health care organization directors should be concerned with the manner in which they carry out their duty to oversee corporate compliance programs. Depending upon the nature of the corporation, there are a variety of parties that might in extreme circumstances seek to hold corporate directors personally liable for allegedly breaching the duty of oversight with respect to corporate compliance. With respect to for-profit corporations, the most likely individuals to bring a case against the directors are corporate shareholders in a derivative suit, or to a limited degree, a regulatory agency such as the Securities and Exchange Commission. With respect to non-profit corporations, the most likely person to initiate such action is the state attorney general, who may seek equitable relief against the director (e.g., removal) or damages. It is also possible (depending upon state law) that a dissenting director, or the corporate member, could assert a derivative-type action against the directors allegedly responsible for the "inattention," seeking removal or damages.

Over the last decade, the risks associated with non-compliance have grown dramatically. The government has dedicated substantial resources, including the addition of criminal investigators and prosecutors, to respond to health care fraud and abuse. In

3 Law is not static, and different states will have different legal developments and standards. Standards may also vary depending on whether an entity is for profit or non-profit. Boards of public health care entities may have additional statutory obligations and should be aware of state and federal statutory requirements applicable to them.

addition to government investigators and auditors, private whistleblowers play an important role in identifying allegedly fraudulent billing schemes and other abusive practices. Health care providers can be found liable for submitting claims for reimbursement in reckless disregard or deliberate ignorance of the truth, as well as for intentional fraud. Because the False Claims Act authorizes the imposition of damages of up to three times the amount of the fraud and civil monetary penalties of $11,000 per false claim, record level fines and penalties have been imposed against individuals and health care organizations that have violated the law.

In addition to criminal and civil monetary penalties, health care providers that are found to have defrauded the federal health care programs may be excluded from participation in these programs. The effect of an exclusion can be profound because those excluded will not receive payment under Medicare, Medicaid or other federal health care programs for items or services provided to program beneficiaries. The authorities of the OIG provide for mandatory exclusion for a minimum of five years for a conviction with respect to the delivery of a health care item or service. The presence of aggravating circumstances in a case can lead to a lengthier period of exclusion. Of perhaps equal concern to board members, the OIG also has the discretion to exclude providers for certain conduct even absent a criminal conviction. Such conduct includes participation in a fraud scheme, the payment or receipt of kickbacks, and failing to provide services of a quality that meets professionally recognized standards. In lieu of imposing exclusion in these instances, the OIG may require an organization to implement a comprehensive compliance program, requiring independent audits, OIG oversight and annual reporting requirements, commonly referred to as a Corporate Integrity Agreement.

IV. The Development of Compliance Programs

In light of the substantial adverse consequences that may befall an organization that has been found to have committed health care fraud, the health care industry has embraced efforts to improve compliance with federal and state health care program requirements. As a result, many health care providers have developed active compliance programs tailored to their particular circumstances. A recent survey by the Health Care Compliance Association, for example, has found that in just three years, health care organizations with active compliance programs have grown from 55 percent in 1999 to 87 percent in 2002. In support of these efforts, the OIG has developed a series of provider-specific compliance guidances. These voluntary guidelines identify risk areas and offer concrete suggestions to improve and enhance an organization's internal controls so that its billing practices and other business arrangements are in compliance with Medicare's rules and regulations.

As compliance programs have matured and new challenges have been identified, health care organization boards of directors have sought ways to help their organization's compliance program accomplish its objectives. Although health care organization directors may come from diverse backgrounds and business experiences, an individual director can make a valuable contribution toward the compliance objective by asking practical questions of management and contributing her experiences from other industries. While the opinion in *Caremark* established a Board's duty to oversee a compliance program, it did not enumerate a specific methodology for doing so. It is therefore important that directors participate in the development of this process. This educational resource is designed to assist health care organization directors in exercising that responsibility.

V. Suggested Questions for Directors

Periodic consideration of the following questions and commentary may be helpful to a health care organization's Board of Directors. The structural questions explore the Board's understanding of the scope of the organization's compliance program. The remaining questions, addressing operational issues, are directed to the operations of the compliance program and may facilitate the Board's understanding of the vitality of its compliance program.

A. 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 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.

2. **How does the organization's compliance reporting system work? How frequently does the Board receive reports about compliance issues?**

   Although the frequency of reports on the status of the compliance program will depend on many circumstances, health care organization Boards should receive reports on a regular basis. Issues that are frequently addressed include (1) what the organization has done in the past with respect to the program and (2) what steps are planned for the future and why those steps are being taken.

3. **What are the goals of the organization's compliance program? What are the inherent limitations in the compliance program? How does the organization address these limitations?**

   The adoption of a corporate compliance program by an organization creates standards and processes that it should be able to rely upon and against which it may be held accountable. A solid understanding of the rationale and objectives of the compliance program, as well as its goals and inherent limitations, is essential if the Board is to evaluate the reasonableness of its design and the effectiveness of its operation. If the Board has unrealistic expectations of its compliance program, it may place undue reliance on its ability to detect vulnerabilities. Furthermore, compliance programs will not prevent all wrongful conduct and the Board should be satisfied that there are mechanisms to ensure timely reporting of suspected violations and to evaluate and implement remedial measures.

4. **Does the compliance program address the significant risks of the organization? How were those risks determined and how are new compliance risks identified and incorporated into the program?**

   Health care organizations operate in a highly regulated industry and must address various standards, government program conditions of participation and reimbursement, and other standards applicable to corporate citizens irrespective of industry. A comprehensive ongoing process of compliance risk assessment is important to the Board's awareness of new challenges to the organization and its evaluation of management's priorities and program resource allocation.

5. **What will be the level of resources necessary to implement the compliance program as envisioned by the Board? How has management determined the adequacy of the resources dedicated to implementing and sustaining the compliance program?**

   From the outset, it is important to have a realistic understanding of the resources necessary to implement and sustain the compliance program as adopted by the Board. The initial investment in establishing a compliance infrastructure and training the organization's employees can be significant. With the adoption of a compliance program, the organization is making a long term commitment of resources because effective compliance systems are not static programs but instead embrace continuous improvement. Quantifying the organization's investment in compliance efforts gives the Board the ability to consider the feasibility of implementation plans against compliance program goals. Such investment may include annual budgetary commitments as well as direct and indirect human resources dedicated to compliance. To help ensure that the organization is realizing a return on its compliance investment, the Board also should consider how management intends to measure the effectiveness of its compliance program. One measure of effectiveness may be the Board's heightened sensitivity to compliance risk areas.

B. Operational Questions

The following questions are suggested to assist the Board in its periodic evaluation of the effectiveness of the organization's compliance program and the sufficiency of its reporting systems.

1. **Code of Conduct—How has the Code of Conduct or its equivalent been incorporated into corporate policies across the organization? How do we know that the Code is understood and accepted across the organization? Has management taken affirmative steps to publicize the importance of the Code to all of its employees?**

   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.

2. **Policies and Procedures—Has the organization implemented policies and procedures that address compliance risk areas and established internal controls to counter those vulnerabilities?**

   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.[4] Regular consultation with counsel, including reports to the Board, can assist the Board in its oversight responsibilities in this changing environment.

3. **Compliance Infrastructure**
   a. **Does the Compliance Officer have sufficient authority to implement the compliance program? Has management provided the Compliance Officer with the autonomy and sufficient resources necessary to perform assessments and respond appropriately to misconduct?**

      Designating and delegating appropriate authority to a compliance officer is essential to the success of the organization's compliance program. For example, the Compliance Officer must have the authority to review all documents and other information that are relevant to compliance activities. Boards should ensure that lines of reporting within management and to the Board, and from the Compliance Officer and consultants, are sufficient to ensure timely and candid reports for those responsible for the compliance program. In addition, the Compliance Officer must have sufficient personnel and financial resources to implement fully all aspects of the compliance program.

   b. **Have compliance-related responsibilities been assigned across the appropriate levels of the organization? Are employees held accountable for meeting these compliance-related objectives during performance reviews?**

      The successful implementation of a compliance program requires the distribution throughout the organization of compliance-related responsibilities. The Board should satisfy itself that management has developed a system that establishes accountability for proper implementation of the compliance program. The experience of many organizations is that program implementation lags where there is poor distribution of responsibility, authority and accountability beyond the Compliance Officer.

4. **Measures to Prevent Violations**
   a. **What is the scope of compliance-related education and training across the organization? Has the effectiveness of such training been assessed? What policies/measures have been developed to enforce training requirements and to provide remedial training as warranted?**

      A critical element of an effective compliance program is a system of effective organization-wide training on compliance standards and procedures. In addition, there should be specific training on identified risk areas, such as claims development and submission and marketing practices. Because it can represent a significant commitment of resources, the Board should understand the scope and effectiveness of the educational program to assess the return on that investment.

   b. **How is the Board kept apprised of significant regulatory and industry developments affecting the organization's risk? How is the compliance program structured to address such risks?**

4 There are a variety of materials available to assist health care organizations in this regard. For example, both sponsoring organizations of this educational resource offer various materials and guidance, accessible through their web sites, www.healthlawyers.org and www.oig.hhs.gov.

The Board's oversight of its compliance program occurs in the context of significant regulatory and industry developments that impact the organization not only as a health care organization but more broadly as a corporate entity. Without such information, it cannot reasonably assess the steps being taken by management to mitigate such risks and reasonably rely on management's judgment.

c. **How are "at risk" operations assessed from a compliance perspective? Is conformance with the organization's compliance program periodically evaluated? Does the organization periodically evaluate the effectiveness of the compliance program?**

Compliance risk is further mitigated through internal review processes. Monitoring and auditing provide early identification of program or operational weaknesses and may substantially reduce exposure to government or whistleblower claims. Although many assessment techniques are available, one effective tool is the performance of regular, periodic compliance audits by internal or external auditors. In addition to evaluating the organization's conformance with reimbursement or other regulatory rules, or the legality of its business arrangements, an effective compliance program periodically reviews whether the compliance program's elements have been satisfied.

d. **What processes are in place to ensure that appropriate remedial measures are taken in response to identified weaknesses?**

Responding appropriately to deficiencies or suspected non-compliance is essential. Failure to comply with the organization's compliance program, or violation of applicable laws and other types of misconduct, can threaten the organization's status as a reliable and trustworthy provider of health care. Moreover, failure to respond to a known deficiency may be considered an aggravating circumstance in evaluating the organization's potential liability for the underlying problem.

5. Measures to Respond to Violations

a. **What is the process by which the organization evaluates and responds to suspected compliance violations? How are reporting systems, such as the compliance hotline, monitored to verify appropriate resolution of reported matters?**

Compliance issues may range from simple overpayments to be returned to the payor to possible criminal violations. The Board's duty of care requires that it explore whether procedures are in place to respond to credible allegations of misconduct and whether management promptly initiates corrective measures. Many organizations take disciplinary actions when a responsible employee's conduct violates the organization's Code of Conduct and policies. Disciplinary measures should be enforced consistently.

b. **Does the organization have policies that address the appropriate protection of "whistleblowers" and those accused of misconduct?**

For a compliance program to work, employees must be able to ask questions and report problems. In its fulfillment of its duty of care, the Board should determine that the organization has a process in place to encourage such constructive communication.

c. **What is the process by which the organization evaluates and responds to suspected compliance violations? What policies address the protection of employees and the preservation of relevant documents and information?**

Legal risk may exist based not only on the conduct under scrutiny, but also on the actions taken by the organization in response to the investigation. In addition to a potential obstruction of a government investigation, the organization may face charges by employees that it has unlawfully retaliated or otherwise violated employee rights. It is important, therefore, that organizations respond appropriately to a suspected compliance violation and, more critically, to a government investigation without damaging the corporation or the individuals involved. The Board should confirm that processes and policies

for such responses have been developed in consultation with legal counsel and are well communicated and understood across the organization.

d. What guidelines have been established for reporting compliance violations to the Board?

As discussed, the Board should fully understand management's process for evaluating and responding to identified violations of the organization's policies, as well as applicable federal and state laws. In addition, the Board should receive sufficient information to evaluate the appropriateness of the organization's response.

e. What policies govern the reporting to government authorities of probable violations of law?

Different organizations will have various policies for investigating probable violations of law. Federal law encourages organizations to self-disclose wrongdoing to the federal government. Health care organizations and their counsel have taken varied approaches to making such disclosures. Boards may want to inquire as to whether the organization has developed a policy on when to consider such disclosures.

VI. Conclusion

The corporate director, whether voluntary or compensated, is a bedrock of the health care delivery system. The oversight activities provided by the director help form the corporate vision, and at the same time promote an environment of corporate responsibility that protects the mission of the corporation and the health care consumers it serves.

Even in this "corporate responsibility" environment, the health care corporate director who is mindful of her fundamental duties and obligations, and sensitive to the premises of corporate responsibility, should be confident in the knowledge that she can pursue governance service without needless concern about personal liability for breach of fiduciary duty and without creating an adversarial relationship with management.

The perspectives shared in this educational resource are intended to assist the health care director in performing the important and necessary service of oversight of the corporate compliance program. In so doing, it is hoped that fiduciary service will appear less daunting and provide a greater opportunity to "make a difference" in the delivery of health care.

I. Introduction

As a supplement to the publication, *Corporate Responsibility and Corporate Compliance,*[1] *(Corporate Compliance*), a joint educational effort of the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) and the American Health Lawyers Association (AHLA), this document addresses the roles of the in-house corporate general counsel (General Counsel) and an organization's Chief Compliance Officer in supporting the compliance oversight function of health care organization governing boards (Boards of Directors or Boards). This supplemental educational resource addresses issues raised by recent developments in the law with respect to corporate responsibility and lawyers' professional ethics, the modifications to the U.S. Sentencing Commission's Federal Sentencing Guidelines for Organizations (Sentencing Guidelines), and the recommendations of the American Bar Association Task Force on Corporate Responsibility (ABA Task Force).[2] It addresses these issues in the unique context of health care compliance and health care law, particularly in light of the expressed view of the OIG regarding the risk of structuring an organization's compliance function as subordinate to the General Counsel function.

Recent developments in the corporate and securities world have refocused attention on effective corporate governance and the role of the General Counsel in promoting ethical conduct and compliance with the law. The health care field has certainly witnessed its share of high profile corporate misconduct cases. While corporate compliance programs are well established in most health care industry segments, they continue to evolve in response to emerging "best practices" and changes in the business environment. All of this suggests that there is value in examining the interplay in the roles of the General Counsel and the Chief Compliance Officer in supporting the Board's compliance oversight responsibilities. Consideration of the role of the General Counsel in overseeing compliance programs has been ongoing. In 1998, the OIG stated the following:

> "The OIG believes that there is some risk to establishing an independent compliance function if that function is subordina[te] to the hospital's [G]eneral [C]ounsel, or comptroller or similar hospital financial officer. Freestanding compliance functions help to ensure independent and objective legal reviews and financial analyses of the institution's compliance efforts and activities. By separating the compliance function from the key management positions of [G]eneral [C]ounsel or chief hospital financial officer (where the size and structure of the hospital make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program."[3]

In a similar vein, in a September 5, 2003, letter to Tenet Healthcare Corporation, United States Senator Charles Grassley (R-IA) observed:

> "Apparently, neither Tenet nor (its General Counsel) saw any conflict in her wearing two hats as Tenet's General Counsel and Chief Compliance Officer . . . . It doesn't take a pig farmer from Iowa to smell the stench of conflict in that arrangement."[4]

On the other hand, when assessing the role of the General Counsel in an organization's corporate governance program, the ABA Task Force recommends that:

> "The [G]eneral [C]ounsel of a public corporation should have primary responsibility for assuring the implementation of an effective legal compliance system under the oversight of the board of directors."[5]

So how do we reconcile these views? What role should the General Counsel play in health care organization corporate compliance? To what extent should Boards seek out and rely upon the organization's Chief Compliance Officer? What should be the relationship between the General Counsel and the Chief Compliance Officer? What can a Board expect regarding interactions with company legal counsel (both in-house and outside) in the new environment of corporate responsibility?

---

1 *Corporate Responsibility and Corporate Compliance,* Office of Inspector General, U.S. Dept. of Health & Human Services and the American Health Lawyers Association, (2003), *available at* www.healthlawyers.org/CorporateCompliance.

2 James H. Cheek, III et al., *Report of the American Bar Association, Task Force on Corporate Responsibility* (March 31, 2003), *available at* http://meetings.abanet.org/webupload/commupload/CL116000/otherlinks_files/ABA_CCMR-RecommendationsforReorganizingtheUSRegulatoryStructure.pdf (last visited Aug. 29, 2011).

3 OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987 (Feb. 23, 1998), *available at* http://www.oig.hhs.gov/authorities/docs/cpghosp.pdf (last visited Aug. 29, 2011).

4 *See,* Grassley Investigates Tenet Healthcare's Use of Federal Tax Dollars, Sept. 8, 2003, *available at* http://grassley.senate.gov/releases/2003/p03r09-08.htm (last visited Aug. 29, 2011).

5 *See supra* note 2, at 32. The Task Force report affirms the application of its recommendations to non-public organizations as well. *Id.* at 31.

In light of the OIG position regarding the separation of the compliance function from the General Counsel, some health care organizations and advisors reportedly have taken a stringent view of this concept of separation, treating it more in the nature of a "requirement." Some have even gone so far as to view an otherwise independent compliance officer with a law degree as potentially undercutting the effectiveness of the compliance program. On the other hand, in light of recent developments in the area of lawyer professional responsibility, some may now believe that persons in the position of General Counsel are mandated to assume responsibility in the compliance area.

In reality, a variety of structures for organizing the compliance function is in place in health care organizations. As reflected in the results of a survey conducted by the American Health Lawyers Association and the Health Care Compliance Association, attached as Appendix A, some organizations operate with the same person serving as General Counsel and Chief Compliance Officer, while others assign these functions to distinct individuals and/or departments. Nevertheless, a board member overseeing the compliance function should understand how the organization is addressing the issue of the roles of the General Counsel and Chief Compliance Officer in the implementation of the organization's compliance program. This supplemental educational resource is intended to provide the conscientious director with additional assistance in evaluating the organization's approach to this important question.

II. The Role of the General Counsel

As discussed at length in *Corporate Responsibility and Corporate Compliance*, directors are entitled to rely, in good faith, on officers, employees, and corporate advisors in fulfilling their duty to exercise active oversight and informed judgment on behalf of the corporation. Consequently, the General Counsel, as well as outside lawyers, plays a critical role in the organizational reporting systems that provide information on compliance issues to management and the Board. The contributions lawyers can make to corporate governance include the role of counselor to the Board as it exercises its critical oversight obligation. In this function, lawyers assist the Board in understanding relevant laws and regulations and in analyzing the associated business risks.

As part of the effort to reinforce the role of lawyers in promoting corporate responsibility and compliance with the law, an ABA Task Force examined the professional conduct of lawyers in internal corporate governance. On March 31, 2003, the Task Force issued its report on corporate responsibility. The report called upon lawyers (specifically, the General Counsel) to "assist in the design and maintenance of the corporation's procedures for promoting legal compliance."[6] The report also enumerated a series of recommended governance "best practices" consistent with this emphasis on the role of lawyers in promoting corporate responsibility and developing practices designed to enhance lawyer/client communication on compliance matters.[7]

These recommendations included assigning to the General Counsel the primary responsibility for assuring an effective legal compliance system. To provide the Board with information and analysis necessary to fulfill its oversight responsibilities, the ABA Task Force recommended that the General Counsel meet regularly and in executive session with a committee composed of independent directors to review and communicate concerns with respect to legal compliance matters faced by the corporation. Additionally, the report suggested the creation of direct lines of communication between outside counsel for the corporation and the General Counsel to inform the General Counsel of potential or ongoing violations of law by the corporation.

The ABA recommendations are provided in the midst of an increased focus on the professional obligations of lawyers to serve the interests of their organizational clients. Simultaneous with the adoption of the corporate governance "best practices" recommendations, the ABA also approved revisions to the Model Rules of Professional Conduct, designed in large part to address the proper role of lawyers in disclosing to internal and external third parties information concerning clients' criminal or fraudulent conduct.[8]

Specifically, Model Rules 1.13, Organization as Client, and 1.6, Confidentiality of Information, attempt to deal more effectively with the extraordi-

6 *Id.* at 21.

7 The report suggests that if a corporation has no internal general counsel, it should identify and designate a lawyer or law firm to act as generalcounsel. *Id.* at 63.

8 *See, supra* note 2, at 77-89. The ABA Model Rules of Professional Conduct emphasize the lawyer's responsibility "[a]s advisor [to] provide a client with an informed understanding of the client's legal rights and obligations and explain their practical implications." *Id.* at 21.

nary scenario in which a corporation may be threatened with the potential for substantial injury due to actual or potential action by a corporate employee. Revisions to Model Rule 1.13 are designed to clarify a lawyer's obligation to communicate with, and report wrongdoing to, a higher organizational authority. Revisions to Model Rule 1.6 are designed to permit disclosure of confidential client information to prevent substantial injury to the corporation. While controversial, these revised Model Rules reflect growing awareness of the role of lawyers in enhancing organizational commitment to corporate responsibility.

III. An Integrated Response to Corporate Compliance

Given its focus on the General Counsel, the ABA Task Force Report did not address specifically the role of the Chief Compliance Officer in promoting the compliance oversight function of the Board. In some respects, the position of a Chief Compliance Officer is unique within a corporate organization. No other person has primary functional responsibility for the day-to-day operations of the compliance and ethics program. The breadth of the responsibilities and roles of a Chief Compliance Officer will vary, but may include: 1) developing and implementing policies, procedures, and practices; 2) overseeing and monitoring the implementation of the program; 3) updating and revising the program, as appropriate; 4) developing, coordinating, and participating in a multi-faceted training and education program; 5) coordinating internal audits; 6) reviewing, responding to, and investigating reports of non-compliance; 7) serving as a resource across the organization on substantive compliance questions and issues; and 8) reporting directly to the Board of Directors, CEO, and president on compliance matters. In that process, the Chief Compliance Officer is expected to have a broad knowledge of the organization and operational matters and an awareness of applicable laws and regulations. Similarly, few individuals in the organization have the breadth of interaction with individuals at all levels of the organization: board, management, employees, and third parties, including federal and state government representatives.

The Chief Compliance Officer of a health care organization may also bring a depth of experience to the position. Even before the recent corporate scandals, the health care industry experienced a decade of scrutiny by regulators and law enforcement agencies. Health care providers operate in a heavily-regulated environment with rules that may carry significant penalties for non-compliance. The government has committed substantial resources to identifying and sanctioning the individuals and entities that defraud and abuse federal and state health care programs. The net result is that the health care industry has advanced further than many other business sectors in establishing compliance and ethics programs and "best practice" standards. This in turn suggests that the roles of the General Counsel and the Chief Compliance Officer in supporting the Board's compliance oversight function may be more complex in the health care industry than in other industry sectors.

Consider, for example, the significant degree to which health care providers, ranging from highly complex health care systems to small physician practices, have implemented systems that promote compliance with federal and state health care program requirements. These systems require a detailed knowledge of particularized health care reimbursement schemes, including Medicare and Medicaid regulations and interpretations and third-party payer rules and policies. In this environment, a multi-disciplinary compliance team is essential in assisting an organization's General Counsel and Chief Compliance Officer in gathering and interpreting pertinent information.

The health care industry may also be distinguished by obligations to disclose the adverse findings of an internal audit or employee misconduct. When a compliance review identifies program violations that result in overpayments or a breach of a legal duty, the organization may be compelled to take steps to ensure that the matter is reported appropriately. While a corporation generally may not have a specific legal duty to disclose a violation of the law, participants in the Medicare and Medicaid programs submit an increasing number of reports, certifying to compliance with program requirements. A provider that certifies compliance with program requirements, having knowledge of an undisclosed infraction, may commit a new offense of making a false statement. Furthermore, there may be specific statutes or regulations that compel a health care provider to report known violations of law as a requirement of state licensure or as a condition of program participation. Finally, a provider that is operating under a Corporate Integrity Agreement, as part of the settlement of a fraud case, agrees to disclose to the OIG substantial overpayments and probable violations of criminal, civil, or administrative laws applicable to any federal health care program for which penalties or exclusion may be authorized.

The failure to appropriately monitor compliance with the complex health care regulatory requirements can, in certain circumstances, lead to the submission of a false claim to a third-party payer or the government. In addition, a health care provider's violation of the prohibitions against certain financial relationships with referral sources may trigger criminal, civil, and administrative liability. The consequences of these and other types of violations range from the requirement to repay any improperly received reimbursement amount with interest to the imposition of severe financial penalties, criminal prosecution, and exclusion from participation in any federal health care program. In light of the severe potential consequences that may result from a lack of adherence to applicable legal requirements, it is essential for a health care organization to have an independent compliance team that has a broad base in terms of training, background, and expertise.

As part of the evolution of compliance programs, compliance officers have established themselves as an essential part of a health care provider's management team. These professionals often have demonstrated an expertise in technical health care reimbursement matters, internal controls, troubleshooting, and remedial measures, and may be the point person for employee concerns about the organization. While these attributes may make compliance officers highly effective, they may also create confusion with the respective roles to be played by the organization's General Counsel and its Chief Compliance Officer. Ironically, the relative maturity of compliance programs within the health care industry may mean that role of the General Counsel in overseeing compliance matters is subject to challenge within the organization.

In this regard, the recent changes to the Sentencing Guidelines provide guidance on the roles and reporting relationships of particular categories of personnel with respect to compliance program responsibilities.[9] The Sentencing Guidelines reaffirm the key principle in *Corporate Responsibility and Corporate Compliance* — to have an effective compliance program, the organization's governing authority must be knowledgeable about the content and operations of the compliance program and exercise reasonable oversight over it.[10]

The new Sentencing Guidelines also provide more specific and exacting requirements for the staffing and operation of compliance and ethics programs. To be considered effective, a program must be the responsibility of high-level personnel who have substantial control over the organization or who have a substantial policy- making role within the organization. While other individuals may be assigned day-to-day operational responsibilities for the program, accountability for the compliance program must rest with upper management.[11] Recognizing the value of an independent voice, free of any potential filtering by senior organization managers, the Sentencing Guidelines direct that, where operational responsibility for the compliance program is delegated, those individuals with day-to-day responsibility must have direct access to the Board of Directors or an appropriate Board committee. Further, reports from the individuals responsible for the dayto-day operations of the compliance program must be provided to the Board at least annually.[12] This admonition to protect the independence of the compliance function makes clear that whether responsibility for the compliance program is assigned to the General Counsel or to a distinct Chief Compliance Officer, individuals with day-to-day responsibilities must have appropriate authority and direct access to the Board of Directors.

IV. Considerations for Health Care Boards

Corporate Responsibility and Corporate Compliance suggested areas of inquiry that directors should pursue with management to ensure that the Board understands the scope of its compliance program and challenges inherent in achieving program goals. The following questions are suggested to ensure that 1) the Board understands the roles of the General Counsel and the Chief Compliance Officer in supporting the Board's oversight function and the organization's corporate compliance program; and 2) appropriate processes are in place

9 On April 13, 2004, the United States Sentencing Commission voted to amend the Sentencing Guidelines. The Commission made the standards for a compliance and ethics program more rigorous and put greater responsibility on boards of directors and executives for the oversight and management of the compliance program. The amendments took effect November 1, 2004. The proposed amendments relating to compliance programs can be found at http://www.ussc.gov/Legal/Amendments/Official_Text/20040501_Amendments.pdf, at 75-90 (last visited Aug. 29, 2011). *See also* http://www.ussc.gov/Legislative_and_Public_Affairs/Newsroom/Press_Releases/20040413_Press_Release.htm (last visited Aug. 29, 2011).

10 U.S. Sentencing Comm'n, Organizational Sentencing Guidelines § 8B2.1, *available at* http://www.ussc.gov/Legal/Amendments/Official_Text/20040501_Amendments.pdf, at 75-90 (last visited Aug. 29, 2011).

11 *Id.* § 8B2.1(b)(2), cmt. n. 3 (2004).

12 *Id.*

to assure the Board that it receives appropriate information and candid assessments arising out of the compliance program in a timely manner. These suggested questions and commentary recognize that Boards may consider a variety of approaches in addressing these issues.

A. To what extent is the General Counsel utilized by the Board to provide relevant advice regarding compliance matters?

Ultimately, the structure of operational responsibilities for the compliance program and the Board's relationship with the General Counsel must assure the Board that it receives appropriate and timely information on organizational compliance with applicable laws. The changes to the Sentencing Guidelines give greater clarity to the responsibilities of corporate boards in this regard. Specifically, the Board must not only be knowledgeable about the corporate compliance program, but also be able to evaluate and recommend modifications to the program in light of ongoing organizational risk assessments. Thus, the Board needs to be knowledgeable of any major risks of unlawful conduct facing the organization to evaluate the adequacy of its compliance program in mitigating those risks. As recognized by the ABA Task Force, the General Counsel is an essential resource to the Board for understanding the organization's legal risks and the adequacy of the compliance program in addressing those risks.

B. Where and how is the General Counsel involved in each of the fundamental elements of the compliance program?

Given the ABA Task Force's recommended role for the General Counsel in compliance and the OIG's expressed concerns regarding compliance officer independence, the Board needs to be sure it understands and agrees with the role of its principal legal advisor in the compliance program's design and operation.

The ABA Task Force suggests that a prudent corporate governance program should utilize the General Counsel to assist in the design and maintenance of the corporation's procedures for promoting legal compliance. In many health care organizations, the Chief Compliance Officer has primary responsibility for the development, coordination, and monitoring of the compliance and ethics program. However, given the diversity of Chief Compliance Officer professional backgrounds, the General Counsel can serve as a critically important program resource. For example, the General Counsel can provide essential insights into government regulations and their policy implications to the organization, and the potential legal consequences of proposed courses of action. The Board's oversight function is enhanced if it understands the complementary roles of the General Counsel and the Chief Compliance Officer in their support of the Board's oversight responsibilities.

C. How does the General Counsel receive notice of, and provide input on, the organization's response to identified or suspected compliance failures?

One of the key features of a compliance program is the appropriate organizational response to suspected violations of law. The nature of the response can have a significant impact on the organization internally, as well as on its relationship with federal and state health care programs and third-party payers. The roles of Chief Compliance Officer and General Counsel are no more acutely interwoven and in potential tension than in this context.

Among the typical Chief Compliance Officer's primary responsibilities are the investigation and coordination of an organization's response to such suspected compliance failures. However, the General Counsel also must play a pivotal role in directing the organization's response to suspected compliance failures, particularly when they may trigger administrative, civil, or criminal liability. The Board needs to understand the distinction in the roles and perspectives of the General Counsel and the Chief Compliance Officer, especially when the Chief Compliance Officer is not a lawyer. Assuring the timely involvement of the General Counsel in assessing the significance of potential violations of law, participating appropriately in the investigation, and evaluating options for resolution will help the Board respond appropriately to these challenges to the integrity of the organization.

D. What are the roles of the organization's Chief Compliance Officer and General Counsel in operating the corporate compliance program? Who has responsibility for reporting to the Board on compliance matters?

The Chief Compliance Officer and the General Counsel may have different, and yet ultimately complementary, responsibilities in the operation of the organization's compliance program. The responsibilities of

the Chief Compliance Officer are detailed in the OIG's Compliance Program Guidances.[13] Although the Chief Compliance Officer may have a legal background, typically she is not acting in the capacity as counsel for the organization.

The amendments to the Sentencing Guidelines make clear that, as part of an effective compliance program, the Chief Compliance Officer must periodically report to the Board on the status of the compliance program, the resources required to maintain its vitality, and the organization's response to identified compliance deficiencies. A direct reporting relationship helps avoid any potential filtering or censoring influence of senior organization managers. As previously discussed, the OIG has expressed concern about the wisdom of the Chief Compliance Officer being subordinate to the General Counsel or Chief Financial Officer. The OIG believes that the independence and objectivity of legal and financial analyses of the corporation's activities are enhanced through a system of checks and balances, which includes separating the compliance function from key management positions, including the General Counsel.

As noted earlier, however, the ABA Task Force suggests that the active involvement of the General Counsel in the compliance program is essential to provide the Board with the information and analysis needed for the directors to discharge their oversight responsibilities. The Task Force also suggests that "counsel . . . should have primary responsibility for assuring the implementation of an effective legal compliance system under the oversight of the [B]oard."[14]

The General Counsel's primary responsibility is to represent the legal interests of the organization by acting as a legal counselor to the organization (through its board of directors, officers, and managers) on a wide variety of topics, including compliance with relevant legal obligations. In the context of the compliance program, the General Counsel serves as an important resource to the compliance staff, as well as to the Board in its exercise of oversight over the organization's compliance systems.

It is the Board's responsibility to reconcile these potentially conflicting views into a complementary set of responsibilities and reporting relationships. Ultimately, the interaction between the General Counsel and the Chief Compliance Officer must support the Board in its oversight responsibilities by ensuring that the Board receives accurate information and candid advice.

E. How is the Board notified when there are disagreements among management, the Chief Compliance Officer and/or the General Counsel relating to the organizational response to specific compliance matters?

Significant disagreements among management, the General Counsel, and the Chief Compliance Officer may arise as the organization considers how to respond to internal compliance evaluations that have potential significant financial and legal consequences for the organization. For example, there may be divergence of opinion regarding whether to report to the government the adverse finding of an internal audit. While such disagreements should not necessarily be resolved at the board level, it is important for the Board to understand how management approaches such issues and receives a consensus on a course of action. Consideration should be given to establishing policies that standardize reporting to the Board on such investigations.

The OIG and the U.S. Sentencing Commission recommend that compliance officers have direct access to the Board of Directors and Chief Executive Officer. The expressed concern is that a reporting line through the General Counsel, Chief Financial Officer, or other senior manager may interject other operational concerns into compliance reviews and financial analyses performed by the Chief Compliance Officer. In many organizations, however, a number of practical and operational reasons may support a Chief Compliance Officer reporting directly to a high-level manager or the General Counsel. If this is the case, it may be in the best interests of the program that the General Counsel or other senior manager not be the sole recipient of compliance reports.
In pursuit of its oversight responsibilities for the compliance program, the Board should reasonably assure itself that the compliance function is appropriately free of undue constraints and that the Chief Compliance Officer is able to provide the Board with objective information, analyses, and recommendations. The concept of "checks and balances" in the compliance reporting process is prudent, regardless of who has formal responsibility for the compliance program. Direct reporting to the Board and alternative reporting processes

13 *See supra* note 3.
14 *See, supra* note 2, at 32.

may also promote the integrity of the compliance program, while respecting the operational preferences of management.

F. Does the Board understand how the organization utilizes the attorney/client and work product privileges when responding to third party requests for information?

Investigations into suspected violations of law can have profound implications for an organization. In this sensitive area, it is important that the Board receive timely and objective information and sound legal advice on proposed courses of action. Judicially-recognized privileges exist to promote candid and confidential communications between the client and its counsel, including the attorney/client and attorney work product privileges.[15] While certain aspects of an attorney's investigation into allegations of misconduct may be protected from disclosure to third parties, the organization's responses to identified material violations of law may involve reporting the misconduct to the appropriate government agency. The cooperation expected from organizations by the government in resolving such matters can give rise to a tension between the sufficiency of such disclosures and the appropriate assertion of these privileges.

From the government's perspective, blanket or routine assertions of the work product or attorney-client privilege in routine auditing and compliance monitoring activities may undermine the vitality of the asserted privilege and diminish the credibility of the compliance program and the organization. It is important, therefore, that the Board receive sound advice on the nature, utility, and limitations of these privilege doctrines and the policies and practices of management and General Counsel in their application.

G. Are processes in place to enable the General Counsel to bring issues of legal compliance to the appropriate authorities within the organization?

The extent of inside and outside counsels' responsibility to report potential violations of law, a breach of duty to the corporation, and other substantial legal concerns is an issue of continuing debate. With the enactment of Sarbanes-Oxley, the SEC has established minimum standards of professional conduct for attorneys appearing and practicing before the Commission, including a requirement to report evidence of material violations of law under certain circumstances "up the ladder" within an organization. Similar obligations are contemplated by the revisions to ABA Model Rules 1.13 and 1.6, which address the circumstances under which an attorney may be ethically obligated to withdraw from the representation of a client.

Although the circumstances giving rise to such "up the ladder" reporting should be extraordinary, it is important that the Board 1) understand these particular responsibilities of counsel to exercise informed professional judgment in determining what steps are reasonably necessary in the best interests of the organization, and 2) ensure that lines of communication are established to enable the General Counsel to report any concerns about significant compliance issues up to the highest levels of authority within the organization. The Board may wish to consider various mechanisms, including periodic executive sessions between the General Counsel and the Board, to ensure that critical compliance issues are brought to its attention.

V. Summary Considerations

Recognizing the important responsibilities of both the General Counsel and the Chief Compliance Officer to every health care organization, the following are certain summary considerations that might enhance a system of checks and balances to help meet the organization's compliance program objectives and program oversight.

A. Where the General Counsel Serves as the Chief Compliance Officer

1. Consider the adoption of a recusal process by which the General Counsel may recuse herself from a compliance investigation, as well as alternative reporting processes, if the matter may implicate the General Counsel. A substantial majority of respondents to the AHLA-HCCA survey reported utilizing such processes.

2. Consider periodic Board initiated third-party audits or assessments of the compliance program, as suggested in the OIG Compliance Program Guidances.
3. Consider authorizing the Board Audit or Compliance Committee to retain outside counsel or consultants with respect to selected matters under Board-approved criteria.

15 It is beyond the scope of this educational resource to address these privileges in any detail. Additional information on the privileges and their restrictions should be obtained from counsel.

B. Where the Chief Compliance Officer is Separate from the General Counsel, but Reports to the General Counsel

1. Consider formally establishing alternative reporting mechanisms to provide the Chief Compliance Officer direct reporting to another member of senior management if the Chief Compliance Officer deems such reporting to be necessary. Such a mechanism provides protections for the Board and the organization against any real or perceived obstruction.
2. Consider procedures to have someone other than the General Counsel authorize the Chief Compliance Officer to pursue compliance investigations, including the right to hire outside counsel. Here, the authority to independently initiate investigations should be balanced by required notice and consultation with the General Counsel.
3. Consider periodic direct reports from the Chief Compliance Officer to the Board, balanced by the General Counsel's prior review and consultation so that both may report to and advise the Board consistent with their responsibilities.

C. Where the Compliance Officer is Separate from and Does Not Report to the General Counsel

1. Consider the benefit of having the General Counsel involved in 1) periodic risk assessments; 2) review of proposed policies and reports on compliance processes; 3) conducting investigations; and 4) devising remedial measures to address violations of law.
2. Consider routine General Counsel reviews of matters being reported to the Board by the Chief Compliance Officer.
3. Consider requiring notice to, and consultation with, the General Counsel where there is independent authority for the Chief Compliance Officer to retain outside counsel and consultants.

VI. Conclusion

The recent developments in corporate accountability, stemming from a series of high profile corporate misconduct cases, including such issues as "up the ladder" reporting, have prompted organizations to refocus on how matters of potential or alleged corporate misconduct are brought to the attention of Boards of Directors. In the heavily-regulated field of health care, however, the roles of the General Counsel and the Chief Compliance Officer in corporate compliance have been a focus of attention for many years. Perhaps, in the end, the current attention being given to these roles by Congress, federal agencies, and the industry is simply an appropriate refocus on the basic principle of the ultimate duty of an attorney or a senior manager to serve the client, which in the corporate context is the corporate organization under the leadership of its Board of Directors.

For health care organizations, the unique operational environment and regulatory requirements mandate coordination between the legal function and the compliance function. As the AHLA-HCCA survey indicates, and as this educational resource has discussed, there are a variety of effective approaches to such coordination, many of which are a matter of current practice. This resource has attempted to assist members of health care organization Boards think through the issues related to 1) the critical role of the General Counsel in support of the Board's oversight responsibility for corporate compliance, by informing the Board about potential problem areas, and advising the Board about applicable legal requirements; 2) the essential part played by Chief Compliance Officers, whose breadth of responsibility, expertise, and experience typically places them in a unique position to assist the Board in determining the effectiveness of the organization's compliance program; and 3) the relationship between the General Counsel and the Chief Compliance Officer, and the development of a system of checks and balances that enhances the ability of these two individuals to contribute their knowledge and skills in a way that furthers the interests of the organization.

Ultimately, it is important that a Board receives a sufficient flow of information to effectively conduct its compliance oversight. Establishing and coordinating the roles and responsibilities of the General Counsel and the Chief Compliance Officer within health care organizations to best serve the organization and best assist the Board in its compliance oversight function is essential. It is the goal of this document to be of assistance to health care Boards in exercising this important responsibility.

APPENDIX A

The American Health Lawyers Association (AHLA) and the Health Care Compliance Association (HCCA) sent out a survey designed to explore the relationship between general counsel and compliance officer in different health care organizations. AHLA sent the survey to 1,964 in-house counsel. HCCA sent the survey to 2,490 members, many of whom work as compliance officers in health care organizations. 429 recipients responded to the survey, a response rate of 9.6%.

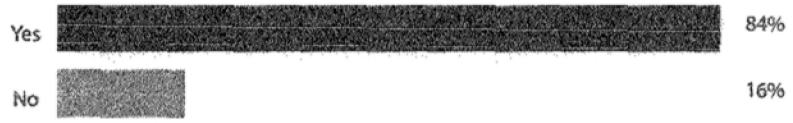
The survey included nine questions for all respondents to answer. It then asked respondents to answer several questions applicable to their particular organizational and reporting structure. The survey included questions for respondents at organizations where the general counsel serves as the compliance officer; where the compliance officer reports to the general counsel; and where the compliance officer does not report to the general counsel.

The responses to the survey provide Board members, CEOs, counsel, compliance officers, and others interested in health care management with insights into the different structures that health care organizations use to manage their compliance activities. The diversity of compliance management structures and reporting relationships reinforce the conclusion that effective Boards will receive regular information and analysis on how their health care organizations manage their compliance activities.

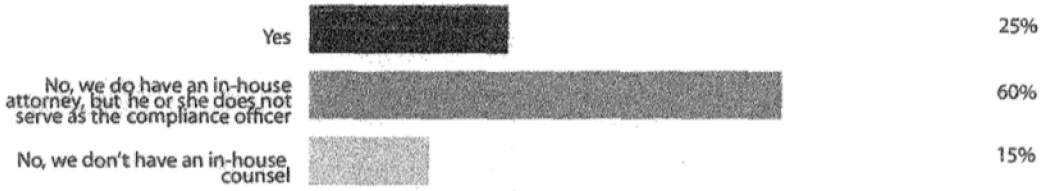
Survey Results

ALL RESPONDENTS ANSWERED THE QUESTIONS IN THIS SECTION.

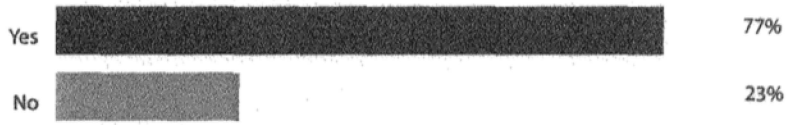
1. Does your organization employ an in-house general counsel or attorney?



2. Does your in-house general counsel or one of your in-house attorneys also serve as the corporate compliance officer?

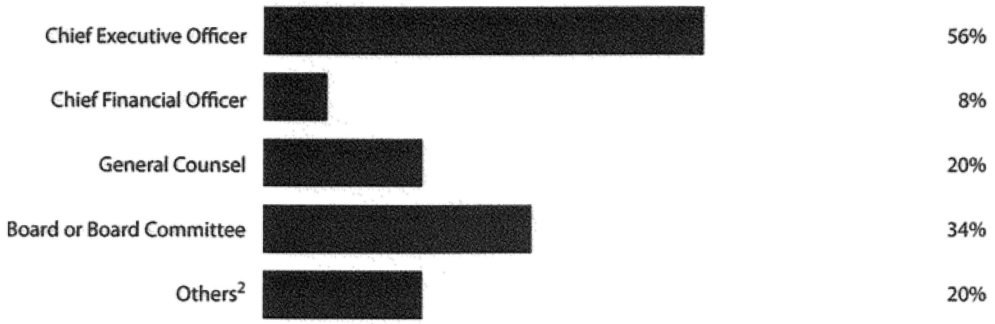


3. Does your organization employ an individual whose principal duty is to act as the corporate compliance officer for the organization?



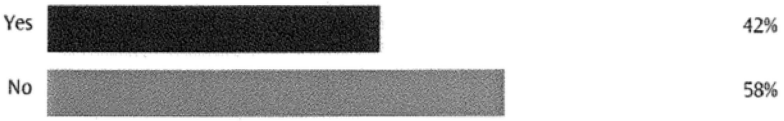
4. Is the corporate compliance officer for your organization also an attorney?

5. To whom does the compliance officer report?[1]



6. If your compliance officer has other official responsibilities within the organization, what are they?

7. If your organization has a compliance officer and not an in-house counsel or in-house attorney, does your organization designate an outside lawyer as the organization's general counsel?



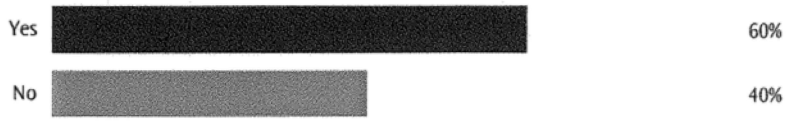
1 Some responses to the survey have a greater than 100% response rate because individual respondents included more than one response for particular questions.

2 Other positions named included VP Government Affairs; Chief Administrative Officer; Audit Committee; Chief Medical Officer; Chief Information Officer; Chief Technology Officer; Vice President Academic Affairs; Dean, College ofMedicine; Chief Operating Officer; VP for Quality; Chief Financial Officer; Risk Manager; and Compliance Advisory Committee.

3 Other responsibilities included risk management; operations officer; public policy; mission effectiveness; security officer; information systems; patient and community relations; quality assurance; business practices; physician relations and contracting; outpatient services; conflict of interest oversight; regulatory affairs; privacy officer; safety officer; limited English proficiency coordinator; research administration; research integrity officer; human protections administrator; social services director; administration; FOIA officer; HIPAA officer; labor relations; IRB; clinical services; and charge description master.

8. Does your organization's Board require that it be informed of any governmental investigation related to an alleged violation of federal or state law?

9. Are internal investigations routinely carried out under the protection of the attorney-client privilege as a matter of policy or practice?



IF THE ORGANIZATION HAS ITS IN-HOUSE GENERAL COUNSEL OR ATTORNEY SERVE AS THE COMPLIANCE OFFICER:

10. Does the organization have a formal policy to allow the in-house general counsel or attorney responsible for compliance independent access to the Board of Directors on a compliance issue if the attorney believes it necessary?

11. Does the organization have a mechanism for the referral of an investigation to an alternative individual if the in-house general counsel or attorney wants to recuse herself from a compliance investigation?

12. Does the organization have a mechanism for allowing an individual with a compliance issue or complaint to bypass the in-house general counsel/attorney if the complaint may implicate the general counsel/attorney?

13. Does the in-house general counsel/attorney report to the Board on compliance issues on a regular basis?

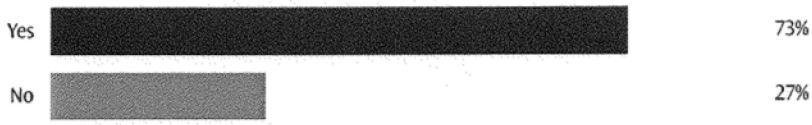
IF THE ORGANIZATION HAS A SEPARATE COMPLIANCE OFFICER WHO REPORTS THROUGH THE IN-HOUSE GENERAL COUNSEL:

14. How does the individual responsible for corporate compliance report through the in-house general counsel?

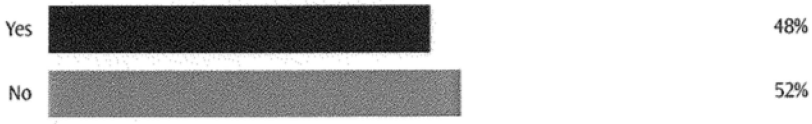
15. Is the compliance officer authorized to pursue compliance investigations without notice to or prior consultation with the general counsel?

16. Has the organization established an alternative mechanism to provide the compliance officer direct reporting to members of senior management if the compliance officer feels such is necessary?

17. Is there a policy/protocol providing for counsel to review/give input on compliance or internal audit matters to be reported to the Board?

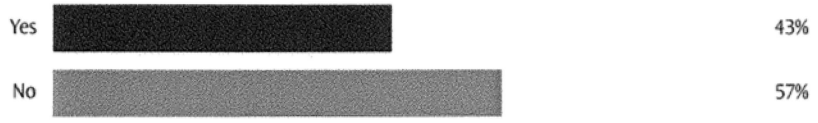


18. Does the organization have a policy or practice of requiring an in-house or outside counsel to conduct/or consult on any compliance investigation?



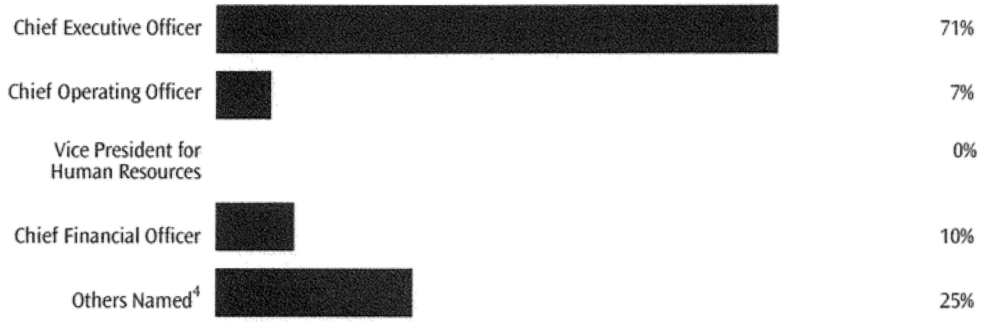
19. Does the compliance officer routinely report directly to the Board at Board meetings on compliance matters?

20. Does the compliance officer have independent authority to retain counsel or other consultants, if he or she believes it necessary?



IF THE ORGANIZATION DOES NOT HAVE ITS COMPLIANCE OFFICER REPORT THROUGH AN IN-HOUSE GENERAL COUNSEL OR ATTORNEY:

21. If the compliance officer does not report to the in-house general counsel or an in-house attorney, to whom does the corporate compliance officer directly report?



22. Does the organization require consultation/review/input between the compliance officer and an in-house general counsel or attorney or an outside counsel prior to a compliance investigation?

23. Does the organization require consultation/review/input between the compliance officer and an in-house or outside attorney if there is a particular red flag during an investigation?

4 Answers similar to those provided in footnote 1.

24. Do the compliance officer and the general counsel/attorney meet formally or informally on a frequent basis (meaning once a week or more)?

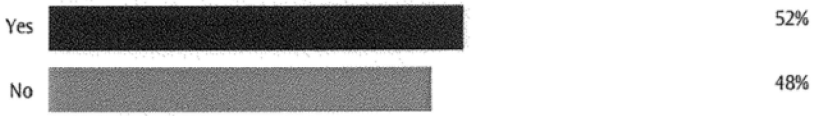
25. Does the compliance officer copy the general counsel/attorney on significant correspondence?

26. Does the compliance officer generally seek advice from the general counsel/attorney when asserting privilege?

27. Does the compliance officer routinely report directly to the Board on compliance matters?

28. Is there a policy/protocol providing for counsel review/input on compliance or internal audit matters to be reported to the Board?

29. Does the compliance officer have independent authority to retain counsel or other consultants?



I. Introduction

This educational resource is the third in a Corporate Responsibilities Series (Series) of co-sponsored documents by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) and the American Health Lawyers Association (AHLA), the leading health law educational organization.[1] It seeks to assist directors of health care organizations in carrying out their important oversight responsibilities in the current challenging health care environment. Improving the knowledge base and effectiveness of those serving on health care organization boards will help to achieve the important goal of continuously improving the U.S. health care system.

The prior publications in this Series addressed the unique fiduciary responsibilities of directors of health care organizations in the corporate compliance context. With a new era of focus on quality and patient safety rapidly emerging, oversight of quality also is becoming more clearly recognized as a core fiduciary responsibility of health care organization directors. Health care organization boards have distinct responsibilities in this area because promoting quality of care and preserving patient safety are at the core of the health care industry and the reputation of each health care organization. The heightened attention being given to health care quality measurement and reporting obligations also increasingly impacts the responsibilities of corporate directors. Indeed, quality is also emerging as an enforcement priority for health care regulators.

The fiduciary duties of directors reflect the expectations of corporate stakeholders regarding oversight of corporate affairs. The basic fiduciary duty of care principle, which requires a director to act in good faith with the care an ordinarily prudent person would exercise under similar circumstances, is being tested in the current corporate climate. Embedded within the duty of care is the concept of reasonable inquiry. In other words, directors are expected to make inquiries to management to obtain the information necessary to satisfy their duty of care.

This educational resource is designed to help health care organization directors ask knowledgeable and appropriate questions related to health care quality requirements, measurement tools, and reporting requirements. The questions raised in this document are not intended to set forth any specific standard of care, nor to foreclose arguments for a change in judicial interpretation of the law or resolution of any conflicts in interpretation among various courts. Rather, this resource will help corporate directors establish, and affirmatively demonstrate, that they have followed a reasonable quality oversight process.

Of course, the circumstances of each organization differ and application of the duty of care and consequent reasonable inquiry by boards will need to be tailored to each specific set of facts and circumstances. However, compliance with standards and regulations applicable to the quality of services delivered by health care organizations is essential for the lawful behavior and corporate success of such organizations. While these evolving requirements can be complex, effective compliance in the quality arena is an asset for both the organization and the health care delivery system. It is hoped that this educational resource is useful to health care organization directors in exercising their oversight responsibilities and supports their ongoing efforts to promote effective corporate compliance as it relates to health care quality.

II. Board Fiduciary Duty and Quality in the Health Care Setting

Governing boards of health care organizations increasingly are called to respond to important new developments—clinical, operational and regulatory—associated with quality of care. Important new policy issues are arising with respect to how quality of care affects matters of reimbursement and payment, efficiency, cost controls, collaboration between organizational providers and individual and group practitioners. These new issues are so critical to the operation of health care organizations that they require attention and oversight, as a matter of fiduciary obligation, by the governing board.

This oversight obligation is based upon the application of the fiduciary duty of care board members owe the organization and, for non-profit organizations, the duty of obedience to charitable mission. It is additive to the traditional duty of board

1 The other two co-sponsored documents in the series are *Corporate Responsibility and Corporate Compliance*, The Office of Inspector General of the U.S. Department of Health and Human Services and The American Health Lawyers Association, 2003; and *An Integrated Approach to Corporate Compliance*, The Office of Inspector General of the U.S. Department of Health and Human Services and The American Health Lawyers Association, 2004, both of which precede this chapter in this guidebook.

members in the hospital setting to be responsible for granting, restricting and revoking privileges of membership in the organized medical staff.

A. Duty of Care

The traditional and well-recognized duty of care refers to the obligation of corporate directors to exercise the proper amount of care in their decision-making process. State corporation laws, as well as the common law, typically interpret the duty of care in an almost identical manner, whether the organization is non-profit or for-profit.

In most jurisdictions, the duty of care requires directors to act (1) in "good faith," (2) with the care an ordinarily prudent person would exercise in like circumstances, and (3) in a manner that they reasonably believe to be in the best interests of the corporation.[2] In analyzing compliance with the duty of care, courts typically address each of these elements individually. In addition, in recent years, the duty of care has taken on a richer meaning, requiring directors to actively inquire into aspects of corporate operations where appropriate – the "reasonable inquiry" standard.

Thus, the "good faith" analysis normally focuses upon whether the matter or transaction at hand involves any improper financial benefit to an individual and/or whether any intent exists to take advantage of the corporation. The "prudent person" analysis focuses upon whether directors conducted the appropriate level of due diligence to allow them to render an informed decision. In other words, directors are expected to be aware of what is going on around them in the corporate business and must in appropriate circumstances make such reasonable inquiry as would an ordinarily prudent person under similar circumstances. The final criterion focuses on whether directors act in a manner that they reasonably believe to be in the best interests of the corporation. In this regard, courts typically evaluate the board member's state of mind with respect to the issues at hand.

When evaluating the fiduciary obligations of board members, it is important to recognize that "perfection" is not the required standard of care. Directors are not required to know everything about a topic they are asked to consider. They may, where justified, rely on the advice of executive leadership and outside advisors.

In addition, many courts apply the "business judgment rule" to determine whether a director's duty of care has been met with respect to corporate decisions. The rule provides, in essence, that a director will not be held liable for a decision made in good faith, where the director is disinterested, reasonably informed under the circumstances, and rationally believes the decision to be in the best interests of the corporation. In other words, courts will not "second guess" the board member's decision when these criteria are met.

Director obligations with respect to quality of care may arise in two distinct contexts:

- The *Decision-Making Function*: The application of duty of care principles as to a specific decision or a particular board action, and
- The *Oversight Function*: The application of duty of care principles with respect to the general activity of the board in overseeing the operations of the corporation (*i.e.*, acting in good faith to assure that a reasonable information and reporting system exists).[3]

Board members' obligations with respect to supervising medical staff credentialing decisions arise within the context of the decision-making function. These are discrete decisions periodically made by the board and relate to specific recommendations and a particular process.

The emerging quality of care issues discussed in this resource arise in the context of the oversight function—the obligation of the director to "keep a finger on the pulse" of the activities of the organization.

The basic governance obligation to guide and support executive leadership in the maintenance of quality of care and patient safety is an ongoing task. Board members are increasingly expected to assess organizational performance on emerging quality of care concepts and arrangements as they implicate issues of patient safety, appropriate levels of care, cost reduction, reimbursement, and collaboration among providers and practitioners. These are all components of the oversight function.

2 American Bar Association, Section of Business Law, Revised Model Nonprofit Corporation Act, Section 8.30 (1987).
3 *In re* Caremark International Inc. Derivative Litigation, 698 A.2d 959 (Del. Ch. 1996).

This duty of care with respect to quality of care also is implicated by the related duty to oversee the compliance program.[4] Many new financial relationships address quality of care issues, including pay-for-performance programs, gainsharing, and outcomes management arrangements, among others. State and federal law closely regulate many of these arrangements. Given that directors have an obligation to assure that the organization has an "effective" compliance program in place to detect and deter legal violations, they may fairly be regarded as having a concomitant duty to make reasonable inquiry regarding the emerging legal and compliance issues associated with quality of care initiatives, and to direct executive leadership to address those issues. The board may direct executive staff to provide periodic briefings to the board with respect to quality of care developments so that the directors may establish a proper "tone at the top" in terms of related legal compliance. In other words, it is the role of the executive staff to brief the board concerning new developments in the law and related legal implications, and it should be the ongoing obligation of the board to reasonably inquire whether the organization's compliance program and other legal control mechanisms are in place to monitor the associated legal risks.

B. Duty of Obedience to Corporate Purpose and Mission

Oversight obligations with respect to quality of care initiatives also arise, for non-profit boards, in the context of what is generally referred to as the fiduciary duty of obedience to the corporate purpose and mission[5] of health care organizations. Non-profit corporations are formed to achieve a specific goal or objective (e.g., the promotion of health), as recognized under state non-profit corporation laws. This is in contrast to the typical business corporation, which often is formed to pursue a general corporate purpose. It is often said of non-profits that "the means and the mission are inseparable."[6]

The fundamental nature of the duty of obedience to corporate purpose is that the non-profit director is charged with the obligation to further the purposes of the organization as set forth in its articles of incorporation or bylaws.[7] For example, the articles of incorporation of a non-profit health care provider might describe its principal purpose as "the promotion of health through the provision of inpatient and outpatient hospital and health care services to residents in the community." Given that the board is responsible for reasonably inquiring whether there are practices in place to address the quality of patient care, it is fair to state that the concept of quality of care is inseparable from, and is essentially subsumed by, the mission of the organization.

In the hospital setting, various provisions of the law dealing with the relationship to the medical staff also provide a link to the duty of obedience to corporate purpose. These include, for example, traditional provisions that confirm the responsibility of the board for (a) the conduct of the hospital as an institution, (b) ensuring that the medical staff is accountable to the governing board for the quality of care provided to patients, and (c) the maintenance of standards of professional care within the facility and requiring that the medical staff function competently. The "duty of obedience" concept with respect to assuring compliance with law also might be considered to incorporate a duty to assure compliance with those state laws (and perhaps accreditation principles as well) that require the governing board to assume ultimate responsibility for organizational performance, which includes the quality of the provider's medical care.

C. Summary

In exercising her duty of care and, as appropriate, duty of obedience to corporate purpose and mission, the governing board member may be expected to exercise general supervision and oversight of quality of care and patient safety issues. This is likely to include (a) being sensitive to the emergence of quality of care issues, challenges and opportunities, (b) being attentive to the development of specific quality of care measurement and reporting requirements (including asking the executive staff for periodic education), and (c) requesting periodic updates from the executive staff on organizational quality of care initiatives and how the organization intends to address legal issues associated with those initiatives. Board members are expected to make reasonable further inquiry

4 *Id.*

5 In some states, this duty is subsumed within the definition of the broader duty of loyalty.

6 Daniel L. Kurtz, Board Liability: Guide for Nonprofit Directors 84 (Moyer Bell Limited, New York, 1988), citing Commonwealth of Pennsylvania v. The Barnes Foundation, 398 Pa. 458, 159 A.2d 500, 505 (1960); *In re* Manhattan Eye, Ear & Throat Hosp., 715 N.Y.S.2d 575 (1999).

7 Kurtz, supra.

when concerns are aroused or should be aroused. These expectations increasingly are becoming more significant with the increased attention to quality of care issues from policy makers, providers and practitioners, payors and regulators. Board members must be, and must be perceived as, responsive to this changing environment.

III. Defining Quality of Care and the Critical Need to Implement Quality Initiatives

> "The American health care delivery system is in need of fundamental change. Many patients, doctors, nurses and health care leaders are concerned that the care delivered is not, essentially, the care we should receive … Quality problems are everywhere affecting many patients. Between the healthcare we have and the care we could have lies not just a gap, but a chasm."[8]

In *Crossing the Quality Chasm*, the Institute of Medicine (IOM) provided a six-part definition of health care quality that some view as the emerging standard. According to the IOM, health care should be: *safe* – avoiding injuries to patients from the care that is intended to help them; *effective* – providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively); *patient-centered* – providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions; *timely* – reducing waits and sometimes harmful delays for both those who receive and those who give care; *efficient* – avoiding waste, including waste of equipment, supplies, ideas, and energy; and *equitable* – providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socio-economic status.[9] Because this definition of quality increasingly is being adopted by payors, providers and regulators, health care organizations and their boards will need to be mindful of its implications.

The U.S. health care system is at a challenging point in its history. It is, for many important historical reasons, a mixed public-private system, and there is no foreseeable dynamic on the horizon suggesting a major change to this reality. The health care system also arguably is driving the U.S. economy. A recent federal forecast predicts that over the next decade, U.S. health care spending will double from today's level to $4.1 trillion and will represent 20% of the gross domestic product.[10] We have a health care system that is extraordinarily advanced, yet is inefficient, uneven, and too often unsafe. A consensus is forming that improvement in the system will require better collaboration and cooperation among independent providers, payors and purchasers, more integrated care, and better aligned incentives. Such collaboration and cooperation inevitably will raise legal compliance issues that health care organization boards of directors will need to understand in exercising their oversight function.

A scorecard on the U.S. health care system developed by the Commonwealth Fund in 2006 showed the following results, among others:[11]

- For 37 key indicators for five health care system dimensions (quality, access, equity, outcomes and efficiencies), the overall U.S. score was 66 out of a possible 100.
- Efficiency was the single worst score among the five dimensions. For example, in 2000/2001, the U.S. ranked 16th out of 20 countries in use of electronic health records.
- The U.S. is the worldwide leader in costs.
- The U.S. scored 15th out of 19 countries in mortality attributable to health care services.
- Basic tools (i.e., Health IT) are missing to track patients through their lives.
- We do poorly at transition stages —hospital readmission rates from nursing homes are high; our reimbursement system encourages "churning."
- Improving performance in key areas would save 100,000 to 150,000 lives and $50 billion to $100 billion annually.

The report makes several key recommendations. The U.S. should expand health insurance coverage; implement major quality and safety improvements; work toward a more organized delivery system that emphasizes primary and preventive care that is patient-centered; increase transparency and reporting on quality and costs; reward performance for quality and efficiency; expand the use of inter-

8 *Crossing the Quality Chasm*, Institute of Medicine, 2001, p.1
9 *Id.* at 6.
10 "Health Care Spending Projected to Pass $4 Trillion Mark by 2016," *Health Affairs*, February 21, 2007.
11 The Commonwealth Fund Commission on a High Performance Health System, "Why Not the Best? Results from a National Scorecard on U.S. Health System Performance," The Commonwealth Fund, September 2006.

operable information technology; and encourage collaboration among stakeholders.

In a similar vein, the IOM recently stated in one of several follow-up reports to *Crossing the Quality Chasm* that the Medicare payment system does not reward efficiency and provides few disincentives for overuse, underuse or misuse of care.[12] Furthermore, the IOM proposed that incentives should encourage delivery of high-quality care efficiently, require providers to assume shared accountability for transitions between care settings and require coordination of care for patients with chronic disease.

We are entering a new era of thinking about health care quality and collaboration among health care providers. Numerous new measures of health care quality are becoming public every day. Purchasers, payors, state governments, the Joint Commission and others are requiring reporting, particularly by hospitals, of outcomes pursuant to such measures. Pay-for-performance programs are becoming common among both public and private payors. A new generation of "gainsharing" proposals and demonstrations are emerging.[13] In late February 2007, HHS Secretary Mike Leavitt unveiled a new quality-improvement plan, called "Value Exchanges," that would establish local quality-improvement collaborations with an eye toward a national link-up in a few years.[14] All of this puts increasing focus and scrutiny on health care organizations, and their boards of directors, in connection with the quality issue. Indeed, the National Quality Forum, perhaps the most well known source of nationally approved quality measures, has issued a paper entitled *Hospital Governing Boards and Quality of Care: A Call to Responsibility.*[15]

Perhaps one of the most critical and often misunderstood components of health care quality is the relationship between overall quality and cost efficiency. Increasingly, it is becoming more widely understood that quality and efficiency are complementary, not contradictory, elements of an effective health care system. Efficiency, by definition, means avoidance of unnecessary, and often harmful, care. As Don Berwick, a recognized national quality expert, stated in *Health Affairs* in 2005, "Right from the start it has been one of the great illusions in the reign of quality that quality and cost go in opposite directions. There remains very little evidence of that."[16]

Because it is coming from the federal government, state government, and private purchasers and payors, the emphasis on collaborative arrangements and cooperation in care giving across independent providers, aggregate payment pools and aligned incentives will require providers to look for legal ways to collaborate and, indeed, align incentives through new financial relationships. In particular, innovative hospital-physician financial relationships, including a variety of formal and informal partnering arrangements, are critical to the achievement of all six of the aims set forth in *Crossing the Quality Chasm.* Examples include pay-for-performance demonstrations, gainsharing initiatives, electronic health record implementation efforts, outpatient care centers, service line joint ventures, and management and leasing arrangements. Evidence-based medicine reasonably can define proper use and increasingly is relied upon to do so. It is expected that the public sector will continue to seek to balance its role as both purchaser and regulator in the search for quality improvement in health care. The private sector at times may have to initiate change before the payment system and regulations catch up, but the rewards are potentially very high—in terms of organizational success as well as social benefit. At the same time, however, legal compliance issues likely will arise in connection with efforts to implement these changes. Health care organizations with oversight by their boards of directors will be required in this regard to be mindful of the anti-kickback statute, the physician self-referral (Stark) law, civil money penalty statutes, the Health Insurance Portability and Accountability Act (HIPAA), federal tax-exemption standards and antitrust law, among other legal areas.

There is an opportunity for the best performers in the industry to create profound change, and then open up these best practices through transparency of data and the promotion of collaboration to spread change. Health care boards of directors have the unique opportunity to take leadership in implementing quality systems that will advance their organizations' respective missions and the

12 *Rewarding Provider Performance: Aligning Incentives in Medicine,* Institute of Medicine, 2007.

13 OIG reviews gainsharing and pay-for-performance programs on a case-by-case basis, and CMS' position on applicability of the Stark Law to such programs is still evolving.

14 Press Release, U.S. Department of Health & Human Services, HHS Secretary Leavitt Unveils Plan for "Value Exchanges" to Report on Health Care Quality and Cost at Local Level (February 28, 2007).

15 "Hospital Governing Boards and Quality of Care: A Call to Responsibility," The National Quality Forum, December 2, 2004.

16 Robert Galvin, "'A Deficiency of Will and Ambition': A Conversation with Donald Berwick," *Health Affairs Web Exclusive,* January 12, 2005.

nation's health. They also have the responsibility to do so in a legally compliant manner.

IV. The Government's Role in Enforcing Health Care Quality

An extensive federal and state regulatory scheme governs the care delivered by health care providers. Designed to promote quality of care, these standards provide a baseline for assessing the level of care provided to the patient and, as discussed previously, increasingly determine the health care provider's reimbursement. For example, Medicare and Medicaid conditions of participation require hospitals to monitor quality through credentialing of medical staff and maintaining effective quality assessment and performance improvement programs. These conditions of participation specify that the medical staff is accountable to a hospital's governing body for the quality of care provided to patients. Long term care providers must meet specific quality of care standards, undergo state surveys, and pass state certifications to participate in government programs. The regulatory framework includes a range of progressive administrative sanctions, including heightened oversight and monetary penalties that may be imposed against providers that fail to comply with the regulatory requirements.

In addition to these administrative remedies, the government enforcement authorities are increasingly focusing on the quality of care provided to beneficiaries of the federal health care programs. The OIG, the U.S. Department of Justice, and state Attorneys General are working collaboratively with the health care regulatory agencies to address the provision of substandard care by individuals and institutions. Sanctions may range from monetary penalties to exclusion from federal and state health care programs and even incarceration for the most serious offenses. For example, a health care provider can be subject to exclusion from the federal health care programs if it provides medically unnecessary services or services that fail to meet professionally recognized standards of care. Even individuals who are not direct care providers, such as hospital administrators and nursing home owners, may be subject to exclusion if they cause others to provide substandard care. Consequently, all levels of a health care organization, from the direct caregiver to the governing body of an institutional provider, could face liability for failing to meet the quality of care obligations applicable to government program providers.

As part of these enforcement efforts, authorities are closely evaluating quality-reporting data. For example, government authorities are increasingly scrutinizing quality data submitted by health care providers to identify inconsistencies and evidence of ongoing quality problems that providers fail to address. Sources of quality-reporting data include, for example, the hospital quality data for the annual payment updates, physician quality-reporting data reported to CMS, medical error and "sentinel event" data reported to the Joint Commission, and quality reporting required under state law. The accuracy of the data submitted to government agencies and third party payors is vital. In addition to relying on such information for monitoring quality and patient safety issues, the federal health care programs increasingly use this data for determining reimbursement, as in the case of the Minimum Data Set in the nursing home setting. Consequently, inaccurate reporting of quality data could result in the misrepresentation of the status of patients and residents, the submission of false claims, and potential enforcement action. As authorities continue to scrutinize quality-reporting data, boards will benefit from ensuring that structures and processes exist within their institution to carefully review this data for accuracy and address potential quality of care issues.

To evaluate the potential risk to the organization, it is important that board members understand the theories of liability relied upon by the government. The predominant criminal and civil fraud theories—medically unnecessary services and "failure of care"—rely on the submission of a claim for reimbursement to the government to establish jurisdiction over the provider. Medicare and Medicaid only cover costs that are reasonable and necessary for the diagnosis or treatment of illness or injury. When medically unnecessary services are provided, the patient is unnecessarily exposed to risks of a medical procedure and the federal health care programs incur needless costs. Hospitals have been subject to prosecution under this theory. For example, a grand jury indicted a Michigan hospital based on its failure to properly investigate medically unnecessary pain management procedures performed by a physician on its medical staff. In another case, a California hospital recently paid $59.5 million to settle civil False Claims Act allegations that the hospital inadequately performed credentialing and peer review of cardiologists on its staff who performed medically unnecessary invasive cardiac procedures.

The second theory of liability involves the provision of care that is so deficient that it amounts to no care at all. This theory derives from the concept commonly applied in the financial fraud context, which subjects providers to liability for billing

government programs for services that were not actually rendered. These cases frequently involve providers, such as nursing homes, that receive "per diem" payments for providing all necessary treatment to patients. For example, a Colorado rehabilitation center entered into a $1.9 million civil False Claims Act settlement to resolve allegations that it provided worthless services to patients, resulting from systemic understaffing at the facility, where deficient services and abuse caused six patient deaths. Federal prosecutors in Missouri charged a long term care facility management company, its CEO, and three nursing homes with conspiracy and health care fraud based on the contention that the defendants imposed budgetary constraints that they knew or should have known would prevent facilities from providing adequate care to residents. The CEO was sentenced to pay $29,000 in criminal fines and to serve an 18-month period of incarceration. The management company and nursing homes were each sentenced to pay $182,250 in criminal fines. In a related civil case, the defendants paid $1.25 million to resolve False Claims Act allegations, and agreed to be excluded from federal health care programs.

This fraud theory also is applied in cases involving violations of regulatory requirements related to quality of care. For example, a Pennsylvania hospital entered into a $200,000 civil False Claims Act settlement to resolve substandard care allegations related to the improper use of restraints.

In addition to substantial civil penalties and criminal fines, health care providers that systematically fail to provide care of an acceptable quality can be excluded from federal health care programs, meaning Medicare and Medicaid will not pay for items or services furnished by the provider. The provision of care that fails to meet accepted standards of care is an enforcement priority for OIG, which is actively pursuing these cases under administrative sanction authorities that explicitly address quality of care. OIG can impose exclusion from the federal health care programs against anyone who furnishes or causes to be furnished medically unnecessary services or services that fail to meet professionally recognized standards of health care.[17] Additionally, OIG is required by law to exclude anyone convicted of patient neglect or abuse.[18]

As part of global settlements of civil health care fraud matters, OIG may negotiate a waiver of the permissive exclusion in exchange for a provider's agreement to enter into a corporate integrity agreement (CIA). In cases involving substandard care, these agreements can involve comprehensive monitoring provisions designed to assess the provider's internal quality improvement infrastructure. A list of the health care providers currently subject to CIAs (including nursing homes, psychiatric facilities, and regional and national chains) is found at the OIG's website, http://oig.hhs.gov/fraud/cias.asp.

A CIA also might entail board-level obligations to help ensure that the organization embraces a commitment to the delivery of quality care. For example, the Tenet Healthcare Corporation board of directors has specific obligations under the organization's current CIA. OIG has required the board to (1) review and oversee the performance of the compliance staff, (2) annually review the effectiveness of the compliance program, (3) engage an independent compliance consultant to assist the board in its review and oversight of Tenet's compliance activities, and (4) submit to OIG a resolution summarizing its review of Tenet's compliance with the CIA and federal health care program requirements. These obligations reflect a growing recognition of the critical role that boards of directors play in ensuring that their organizations promote quality, ensure patient safety, and are in compliance with the obligations of government health care programs.

V. Health Care Board Fiduciary Duty and Quality

Health care is unique in representing both a social good and an economic commodity. Boards of directors of many health care organizations have been called upon to see that their organization's approach those realities in concert, not in competition, with each other. These boards understand that the quality of the products and services their organizations provide can have life or death implications. Health care organizations generally view themselves as mission-driven and health care quality is a key component of that mission.
Yet, the Institute of Medicine's recognition in 1999 that medical errors lead to as many as 100,000 deaths per year served as a wake-up call. Evolving evidence and research into best practices and outcomes measures have provided the impetus to today's rapidly growing "quality movement," which is triggering a whole variety of mandatory and voluntary activities by health care organizations to improve quality and reduce costs.

17 42 U.S.C. § 1320a-7(b)(6)(B).
18 42 U.S.C. § 1320a-7(a)(2).

These new programs and requirements raise the stakes for health care organizations, both financially and legally. Poor quality and value, or the failure to demonstrate good quality and value, increasingly may affect the viability of health care providers, products manufacturers and others. Law enforcement agencies are increasing their scrutiny of providers that deliver substandard care to federal health care beneficiaries. On the other hand, demonstrated quality and value likely will have a positive mission as well as financial effect. Accurate measurement and reporting—indeed, effective compliance with an evolving set of obligations—will be required.

Directors will need to understand this evolving reality and, if they have not already done so, elevate quality as newly defined to the same level of focus that financial viability and regulatory compliance currently command. The next section of this resource provides directors with certain questions that may assist them in exercising their oversight responsibilities in this increasingly important area.

VI. Suggested Questions for Directors

Boards of Directors can play a critical role in advancing the clinical improvement initiatives in their organizations. To realize its full potential, a board needs to develop an understanding of the relevant quality and patient safety issues and then focus on performance goals that drive the organization to provide the best quality and most efficient care. The following series of suggested questions may be helpful as the board examines the scope and operation of the organization's quality and safety initiatives.

A. What are the goals of the organization's quality improvement program? What metrics and benchmarks are used to measure progress towards each of these performance goals? How is each goal specifically linked to management accountability?

There are a growing number of national public and private initiatives directed at promoting quality of care, patient safety, and the corresponding reduction in medical errors. These initiatives rely on clinical care benchmarks to facilitate oversight and promote improved quality outcomes. Such benchmarks, used in conjunction with industry-wide reported data, can provide a context for creating quality of care goals, aligning organizational incentives, and providing a framework for management's reports to the board. Once these parameters are defined, the board can more readily hold management accountable for meeting the organization's quality performance goals.

B. How does the organization measure and improve the quality of patient/resident care? Who are the key management and clinical leaders responsible for these quality and safety programs?

As a threshold matter, the board may wish to confirm its understanding of the structures and processes the organization relies upon to oversee and improve clinical quality and patient safety. Only after it has a complete understanding of how the organization's quality assurance functions operate can the board evaluate the breadth and effectiveness of a quality improvement program. The organizational assessment also can provide a common basis from which management and the board can evaluate these processes against current and emerging regulatory requirements.

C. How are the organization's quality assessment and improvement processes integrated into overall corporate policies and operations? Are clinical quality standards supported by operational policies? How does management implement and enforce these policies? What internal controls exist to monitor and report on quality metrics?

Consistent with the fundamental fiduciary responsibility of oversight, the board has responsibility for institutional policies and procedures relative to quality of care. Increasingly, common law recognizes among a board's non-delegable duties the duty to formulate, adopt, and enforce adequate rules and policies to ensure quality care for all of the organization's patients and residents. Although boards appropriately may utilize the expertise of the medical staff and other professionals to address professional competency and quality issues, these professionals should work actively with the board to advance the institution's quality agenda, to identify systemic deficiencies and to make appropriate recommendations for action. Periodic reviews with management of the quality of care provided to patients and evaluations of the adequacy of these policies in light of evolving standards, clinical practices, and claims experience or trends are consistent with board responsibilities.

D. Does the board have a formal orientation and continuing education process that helps members appreciate external quality and patient safety requirements? Does the board include members with expertise in patient safety and quality improvement issues?

In an era of increasing governance accountability, the boards of health care organizations are expected to understand and be involved in the assessment of performance on quality and patient safety initiatives of their organizations. An understanding of clinical quality measurements, the ability to read quality scorecards and spot red flags, and an appreciation of quality of care as a corporate governance issue may be critical to an effective board. Equally important, board members need a general understanding of national trends in health care quality. Collectively, these skills will enable the board to appreciate the interrelationship of patient safety, health care quality and performance measurement, as well as the business case for quality. For the same reasons a board has financial experts on its audit committee, health care organizations that provide or arrange for goods or services need members with competencies in quality and patient safety issues. With such resources, the board is better positioned to call for and evaluate meaningful quality information using recognized performance metrics from which to evaluate the organization's clinical quality performance.

E. What information is essential to the board's ability to understand and evaluate the organization's quality assessment and performance improvement programs? Once these performance metrics and benchmarks are established, how frequently does the board receive reports about the quality improvement efforts?

The board should consider the nature and level of information it needs to oversee the quality of care in the organization. If there are too many quality indicators, the data may become overwhelming and the critical measures of success may be overlooked. The board may want to work with management and the organization's medical leadership to identify a focused number of vital indicators that are probative of quality or indicative of changes in quality of patient care. In determining which performance measures to include in its "dashboard," the board may want to consider the quality data reviewed by government agencies, the information subject to mandatory reporting requirements, and relevant industry benchmarks.

As part of its oversight of the quality of care delivered by subsidiaries, parent or system boards may have different information needs. While a grounding in quality and patient safety initiatives remains important, the parent board appropriately may rely on local boards to oversee clinical quality of the local facilities under its purview. In large health care systems, the parent board may exercise its governance responsibilities by focusing on the effectiveness of the local boards.

F. How are the organization's quality assessment and improvement processes coordinated with its corporate compliance program? How are quality of care and patient safety issues addressed in the organization's risk assessment and corrective action plans?

As discussed in *Corporate Responsibility and Corporate Compliance*,[19] an effective corporate compliance program can be instrumental in the board's exercise of its fiduciary duty of care. Increasingly, monitoring quality and patient safety issues is recognized as integral to promoting corporate compliance, as well as to risk management and organizational reputation. Use of regulatory compliance processes to continually assess the organization's quality performance can assist in exposing deficiency patterns, which if not recognized and addressed in a timely and effective manner, may expose the organization to enforcement action. Accordingly, as quality improvement takes on increased significance in the organization's compliance program, the board may want to assure itself that the compliance officer is collaborating with the organization's clinical leadership.

G. What processes are in place to promote the reporting of quality concerns and medical errors and to protect those who ask questions and report problems? What guidelines exist for reporting quality and patient safety concerns to the board?

A lack of transparency in the organization's response to concerns about quality and patient safety can contribute to a culture where problems are not addressed and are therefore likely to reoccur. Improving the effectiveness and safety of

19 *See supra* note 1.

services and quality of care requires participation by clinical staff at all levels. In fulfilling its duty of care, the board should consider verifying that the organization has a mechanism to encourage constructive criticism and reporting of errors. Effective compliance programs are structured to address "whistleblower" reporting and protections, and the organization should consider incorporating the reporting of quality and patient safety concerns into both existing compliance procedures and general operating practices.

H. Are human and other resources adequate to support patient safety and clinical quality? How are proposed changes in resource allocation evaluated from the perspective of clinical quality and patient care? Are systems in place to provide adequate resources to account for differences in patient acuity and care needs?

Participation in the federal health care programs requires that the health care organization deliver care of a quality that meets professionally recognized standards of care. When investigating allegations of substandard quality of care, the government will scrutinize whether the health care provider devoted sufficient resources to ensure that the care provided to patients or residents met basic quality requirements. Inadequate levels of professional and support staff, for example, may result in a pattern of substandard care. As part of its annual review of the organization's operating plans and budget, the board should consider the impact of these resource allocation decisions on the quality of care and patient safety. For the same reason, the board should ensure that management has assessed the impact of staff reductions or other budget constraints on quality of care.

A companion area for oversight relates to approvals of new services and significant technology acquisitions. Inquiry regarding the scientific bases supporting the efficacy and safety of new services and the identification of supportive processes to ensure quality and safety of new technology and services may serve to protect financial resources as well as patient safety.

I. Do the organization's competency assessment and training, credentialing, and peer review processes adequately recognize the necessary focus on clinical quality and patient safety issues?

Boards rely heavily on the expertise of their medical staff and the integrity and comprehensiveness of its competency assessment and training, credentialing, and peer review processes to ensure the competency of clinical staff. Alignment of professional staff credentialing standards with quality data can advance a quality-driven model for the professional staff and allows the organization to take appropriate action when significant quality deficiencies are identified.

J. How are "adverse patient events" and other medical errors identified, analyzed, reported, and incorporated into the organization's performance improvement activities? How do management and the board address quality deficiencies without unnecessarily increasing the organization's liability exposure?

Providers operate under significant federal and state requirements relating to quality reporting and improvement. Hospitals, for example, are required to maintain an effective, data-driven quality assessment and improvement program as a condition of participation in the Medicare program. These programs must track quality indicators, including adverse patient events, and set performance improvement priorities that focus on high-risk or problem-prone areas. A growing number of states have mandatory reporting systems for at least some forms of adverse events occurring in acute care hospitals. For example, some states are mandating the reporting of "never events," those errors in medical care that are clearly identifiable, preventable and serious in their consequences for patients. Examples of "never events" include surgery on the wrong body part, a mismatched blood transfusion, and severe "pressure ulcers" acquired in the hospital. In addition, there are other reporting requirements, including the peer review reporting provisions of the Health Care Quality Improvement Act, state peer review statutes, and the privilege and confidentiality provisions of the Patient Safety and

Quality Improvement Act of 2005. Although the application of these statutes to medical staff credentialing, peer review, and broader quality reporting and improvement activities may be challenging, greater organizational risks may lie in the failure to address known or foreseeable quality deficiencies.

Obviously, corporate boards and managers need to evaluate and address quality and patient safety issues but without unnecessarily increasing organizational exposure to liability resulting from the provision of deficient care. It is therefore important for the board to understand the scope of federal and state statutory protections given certain quality-related activities and to make reasonable inquiry to assure that management and the medical staff effectively manage this issue. A discussion with legal counsel on this topic may be helpful.

VII. Conclusion

Contemporary health care quality, patient safety, and cost efficiency initiatives provide an opportunity for health care organizations to make a positive difference to society while promoting their missions and enhancing their financial success. However, health care boards of directors will need to exercise their oversight responsibilities in this area diligently and assure that their organizations are pursuing these opportunities in compliance with evolving legal requirements. The comments and perspectives shared in this educational resource will, it is hoped, assist health care organization boards in exercising their duty of care as it relates to health care quality effectively, efficiently, and in a manner that will help improve the nation's health care system.

1620 Eye Street, NW, 6th Floor
Washington, DC 20006-4010
(202) 833-1100
www.healthlawyers.org

Public Information Series

Educating our members, their clients and local communities on important health law issues

www.healthlawyers.org/PublicInterest

Practical Guidance for Health Care Governing Boards on Compliance Oversight

Office of Inspector General,
U.S. Department of Health and Human Services
Association of Healthcare Internal Auditors
American Health Lawyers Association
Health Care Compliance Association

About the Organizations

This educational resource was developed in collaboration between the Association of Healthcare Internal Auditors (AHIA), the American Health Lawyers Association (AHLA), the Health Care Compliance Association (HCCA), and the Of¿ce of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS).

AHIA is an international organization dedicated to the advancement of the health care internal auditing profession. The AHLA is the Nation's largest nonpartisan, educational organization devoted to legal issues in the health care ¿eld. HCCA is a member-based, nonpro¿t organization serving compliance professionals throughout the health care ¿eld. OIG's mission is to protect the integrity of more than 100 HHS programs, including Medicare and Medicaid, as well as the health and welfare of program bene¿ciaries.

The following individuals, representing these organizations, served on the drafting task force for this document:

Katherine Matos, Senior Counsel, OIG, HHS

Felicia E. Heimer, Senior Counsel, OIG, HHS

Catherine A. Martin, Principal, Ober | Kaler (AHLA)

Robert R. Michalski, Chief Compliance Of¿cer,
Baylor Scott & White Health (AHIA)

Daniel Roach, General Counsel and Chief
Compliance Of¿cer, Optum360 (HCCA)

Sanford V. Teplitzky, Principal, Ober | Kaler (AHLA)

Published on April 20, 2015.

This document is intended to assist governing boards of health care organizations (Boards) to responsibly carry out their compliance plan oversight obligations under applicable laws. This document is intended as guidance and should not be interpreted as setting any particular standards of conduct. The authors recognize that each health care entity can, and should, take the necessary steps to ensure compliance with applicable Federal, State, and local law. At the same time, the authors also recognize that there is no uniform approach to compliance. No part of this document should be taken as the opinion of, or as legal or professional advice from, any of the authors or their respective agencies or organizations.

Table of Contents

Introduction 1

Expectations for Board Oversight of Compliance Program Functions 2

Roles and Relationships 6

Reporting to the Board 9

Identifying and Auditing Potential Risk Areas 11

Encouraging Accountability and Compliance 13

Conclusion 15

Bibliography 16

Introduction

Previous guidance[1] 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. Given heightened industry and professional interest in governance and transparency issues, this document seeks to provide practical tips for Boards as they work to effectuate their oversight role of their organizations' compliance with State and Federal laws that regulate the health care industry. Speci¿cally, this document addresses issues relating to a Board's oversight and review of compliance program functions, including the: (1) roles of, and relationships between, the organization's audit, compliance, and legal departments; (2) mechanism and process for issue-reporting within an organization; (3) approach to identifying regulatory risk; and (4) methods of encouraging enterprise-wide accountability for achievement of compliance goals and objectives.

A critical element of effective oversight is the process of asking the right questions....

1 OIG and AHLA, Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors (2003); OIG and AHLA, An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Boards of Directors (2004); and OIG and AHLA, Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors (2007).

Expectations for Board Oversight of Compliance Program Functions

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.[2] The existence of a corporate reporting system is a key compliance program element, which not only keeps the Board informed of the activities of the organization, but also enables an organization to evaluate and respond to issues of potentially illegal or otherwise inappropriate activity.

Boards are encouraged to use widely recognized public compliance resources as benchmarks for their organizations. The Federal Sentencing Guidelines (Guidelines),[3] OIG's voluntary compliance program guidance documents,[4] and OIG Corporate Integrity Agreements (CIAs) can be used as baseline assessment tools for Boards and management in determining what speci¿c functions may be necessary to meet the requirements of an effective compliance program. The Guidelines "offer incentives to organizations to reduce and ultimately eliminate criminal conduct by providing a structural foundation from which an organization may self-police its own conduct through an effective compliance and ethics program."[5] The compliance program guidance documents were developed by OIG to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. CIAs impose speci¿c structural and reporting requirements to

---

2 In re Caremark Int'l, Inc. Derivative Litig., 698 A.2d 959 (Del. Ch. 1996).

3 U.S. Sentencing Commission, Guidelines Manual (Nov. 2013) (USSG), http://www.ussc.gov/sites/default/files/pdf/guidelines-manual/2013/manual-pdf/2013_Guidelines_Manual_Full.pdf.

4 OIG, Compliance Guidance, http://oig.hhs.gov/compliance/compliance-guidance/index.asp.

5 USSG Ch. 8, Intro. Comment.

promote compliance with Federal health care program standards at entities that have resolved fraud allegations.

Basic CIA elements mirror those in the Guidelines, but a CIA also includes obligations tailored to the organization and its compliance risks. Existing CIAs may be helpful resources for Boards seeking to evaluate their organizations' compliance programs. OIG has required some settling entities, such as health systems and hospitals, to agree to Board-level requirements, including annual resolutions. These resolutions are signed by each member of the Board, or the designated Board committee, and detail the activities that have been undertaken to review and oversee the organization's compliance with Federal health care program and CIA requirements. OIG has not required this level of Board involvement in every case, but these provisions demonstrate the importance placed on Board oversight in cases OIG believes reÀect serious compliance failures.

Although compliance program design is not a "one size ¿ts all" issue, Boards are expected to put forth a meaningful effort....

Although compliance program design is not a "one size ¿ts 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 ¿rst step.

One area of inquiry for Board members of health care organizations should be the scope and adequacy of the compliance program in light of the size and complexity of their organizations. The Guidelines allow for variation according to "the size of the organization."[6] In accordance with the Guidelines,

6 USSG § 8B2.1, comment. (n. 2).

OIG recognizes that the design of a compliance program will depend on the size and resources of the organization.[7] Additionally, the complexity of the organization will likely dictate the nature and magnitude of regulatory impact and thereby the nature and skill set of resources needed to manage and monitor compliance.

While smaller or less complex organizations must demonstrate the same degree of commitment to ethical conduct and compliance as larger organizations, the Government recognizes that they may meet the Guidelines requirements with less formality and fewer resources than would be expected of larger and more complex organizations.[8] Smaller organizations may meet their compliance responsibility by "using available personnel, rather than employing separate staff, to carry out the compliance and ethics program." Board members of such organizations may wish to evaluate whether the organization is "modeling its own compliance and ethics programs on existing, well-regarded compliance and ethics programs and best practices of other similar organizations."[9] The Guidelines also foresee that Boards of smaller organizations may need to become more involved in the organizations' compliance and ethics efforts than their larger counterparts.[10]

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. With an understanding of the dynamic regulatory environment, Boards will be in a position to ask more pertinent questions of management

---

7 Compliance Program for Individual and Small Group Physician Practices, 65 Fed. Reg. 59434, 59436 (Oct. 5, 2000) ("The extent of implementation [of the seven components of a voluntary compliance program] will depend on the size and resources of the practice. Smaller physician practices may incorporate each of the components in a manner that best suits the practice. By contrast, larger physician practices often have the means to incorporate the components in a more systematic manner."); Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14,289 (Mar. 16, 2000) (recognizing that smaller providers may not be able to outsource their screening process or afford to maintain a telephone hotline).

8 USSG § 8B2.1, comment. (n. 2).

9 Id.

10 Id.

and make informed strategic decisions regarding the organizations' compliance programs, including matters that relate to funding and resource allocation. For instance, new standards and reporting requirements, as required by law, may, but do not necessarily, result in increased compliance costs for an organization. Board members may also wish to take advantage of outside educational programs that provide them with opportunities to develop a better understanding of industry risks, regulatory requirements, and how effective compliance and ethics programs operate. In addition, Boards may want management to create a formal education calendar that ensures that Board members are periodically educated on the organizations' highest risks.

Finally, 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 ful¿ll its oversight obligations. Board members are generally entitled to rely on the advice of experts in ful¿lling their duties.[11] OIG sometimes requires entities under a CIA to retain an expert in compliance or governance issues to assist the Board in ful¿lling its responsibilities under the CIA.[12] Experts can assist Boards and management in a variety of ways, including the identi¿cation of risk areas, provision of insight into best practices in governance, or consultation on other substantive or investigative matters.

---

11 See Del Code Ann. tit. 8, § 141(e) (2010); ABA Revised Model Business Corporation Act, §§ 8.30(e), (f)(2) Standards of Conduct for Directors.

12 See Corporate Integrity Agreements between OIG and Halifax Hospital Medical Center and Halifax Staf¿ng, Inc. (2014, compliance and governance); Johnson & Johnson (2013); Dallas County Hospital District d/b/a Parkland Health and Hospital System (2013, compliance and governance); Forest Laboratories, Inc. (2010); Novartis Pharmaceuticals Corporation (2010); Ortho-McNeil-Janssen Pharmaceuticals, Inc. (2010); Synthes, Inc. (2010, compliance expert retained by Audit Committee); The University of Medicine and Dentistry of New Jersey (2009, compliance expert retained by Audit Committee); Quest Diagnostics Incorporated (2009); Amerigroup Corporation (2008); Bayer HealthCare LLC (2008); and Tenet Healthcare Corporation (2006; retained by the Quality, Compliance, and Ethics Committee of the Board).

Roles and Relationships

Organizations should de¿ne the interrelationship of the audit, compliance, and legal functions in charters or other organizational documents. The structure, reporting relationships, and interaction of these and other functions (e.g., quality, risk management, and human resources) should be included as departmental roles and responsibilities are de¿ned. One approach is for the charters to draw functional boundaries while also setting an expectation of cooperation and collaboration among those functions. One illustration is the following, recognizing that not all entities may possess suf¿cient resources to support this structure:

The compliance function promotes the prevention, detection, and resolution of actions that do not conform to legal, policy, or business standards. This responsibility includes the obligation to develop policies and procedures that provide employees guidance, the creation of incentives to promote employee compliance, the development of plans to improve or sustain compliance, the development of metrics to measure execution (particularly by management) of the program and implementation of corrective actions, and the development of reports and dashboards that help management and the Board evaluate the effectiveness of the program.

The legal function advises the organization on the legal and regulatory risks of its business strategies, providing advice and counsel to management and the Board about relevant laws and regulations that govern, relate to, or impact the organization. The function also defends the organization in legal proceedings and initiates legal proceedings against other parties if such action is warranted.

The internal audit function provides an objective evaluation of the existing risk and internal control systems and framework within an organization. Internal audits ensure monitoring functions are working as intended and identify where management monitoring and/or additional

Board oversight may be required. Internal audit helps management (and the compliance function) develop actions to enhance internal controls, reduce risk to the organization, and promote more effective and ef¿cient use of resources. Internal audit can ful¿ll the auditing requirements of the Guidelines.

The human resources function manages the recruiting, screening, and hiring of employees; coordinates employee bene¿ts; and provides employee training and development opportunities.

The quality improvement function promotes consistent, safe, and high quality practices within health care organizations. This function improves ef¿ciency and health outcomes by measuring and reporting on quality outcomes and recommends necessary changes to clinical processes to management and the Board. Quality improvement is critical to maintaining patient-centered care and helping the organization minimize risk of patient harm.

Boards should be aware of, and evaluate, the adequacy, independence,[13] and performance of different functions within an organization on a periodic basis. OIG believes an organization's Compliance Of¿cer should neither be counsel for the provider, nor be subordinate in function or position to counsel or the legal department, in any manner.[14] While independent, an organization's counsel and compliance of¿cer should collaborate to further the interests of the organization. OIG's position on separate compliance and legal functions reÀects the independent roles and professional obligations of each function;[15]

---

13 Evaluation of independence typically includes assessing whether the function has uninhibited access to the relevant Board committees, is free from organizational bias through an appropriate administrative reporting relationship, and receives fair compensation adjustments based on input from any relevant Board committee.

14 See OIG and AHLA, An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Boards of Directors, 3 (2004) (citing Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8,987, 8,997 (Feb. 23, 1998)).

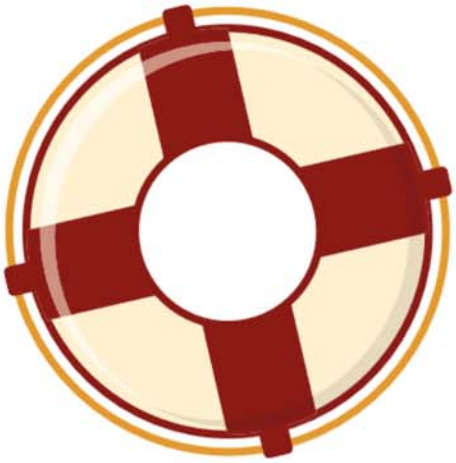
15 See, generally, id.

the same is true for internal audit.[16] To operate effectively, the compliance, legal, and internal audit functions should have access to appropriate and relevant corporate information and resources. As part of this effort, organizations will need to balance any existing attorney-client privilege with the goal of providing such access to key individuals who are charged with the responsibility for ensuring compliance, as well as properly reporting and remediating any violations of civil, criminal, or administrative law.

The Board should have a process to ensure appropriate access to information; this process may be set forth in a formal charter document approved by the Audit Committee of the Board or in other appropriate documents. Organizations that do not separate these functions (and some organizations may not have the resources to make this complete separation) should recognize the potential risks of such an arrangement. To partially mitigate these potential risks, organizations should provide individuals serving in multiple roles the capability to execute each function in an independent manner when necessary, including through reporting opportunities with the Board and executive management.

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.



16 Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8,987, 8,997 (Feb. 23, 1998) (auditing and monitoring function should "[b]e independent of physicians and line management"); Compliance Program Guidance for Home Health Agencies, 63 Fed. Reg. 42,410, 42,424 (Aug. 7, 1998) (auditing and monitoring function should "[b]e objective and independent of line management to the extent reasonably possible"); Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14,289, 14,302 (Mar. 16, 2000).

Boards should understand how management approaches conÀicts or disagreements with respect to the resolution of compliance issues and how it decides on the appropriate course of action. The audit, compliance, and legal functions should speak a common language, at least to the Board and management, with respect to governance concepts, such as accountability, risk, compliance, auditing, and monitoring. Agreeing on the adoption of certain frameworks and de¿nitions can help to develop such a common language.

Reporting to the Board

The Board should set and enforce expectations for receiving particular types of compliance-related information from various members of management. The Board should receive regular reports regarding the organization's risk mitigation and compliance efforts—separately and independently—from a variety of key players, including those responsible for audit, compliance, human resources, legal, quality, and information technology. By engaging the leadership team and others deeper in the organization, the Board can identify who can provide relevant information about operations and operational risks. It may be helpful and productive for the Board to establish clear expectations for members of the management team and to hold them accountable for performing and informing the Board in accordance with those expectations. The Board may request the development of objective scorecards that measure how well management is executing the compliance program, mitigating risks, and implementing corrective action plans. Expectations could also include reporting information on internal and external investigations, serious issues raised in internal and external audits, hotline call activity, all allegations of material fraud or senior management misconduct, and all management exceptions to the organization's

The Board should receive regular reports regarding the organization's risk mitigation and compliance efforts....

code of conduct and/or expense reimbursement policy. In addition, the Board should expect that management will address signi¿cant regulatory changes and enforcement events relevant to the organization's business.

Boards of health care organizations should receive compliance and risk-related information in a format suf¿cient to satisfy the interests or concerns of their members and to ¿t their capacity to review that information. Some Boards use tools such as dashboards—containing key ¿nancial, operational and compliance indicators to assess risk, performance against budgets, strategic plans, policies and procedures, or other goals and objectives—in order to strike a balance between too much and too little information. For instance, Board quality committees can work with management to create the content of the dashboards with a goal of identifying and responding to risks and improving quality of care. Boards should also consider establishing a risk-based reporting system, in which those responsible for the compliance function provide reports to the Board when certain risk-based criteria are met. The Board should be assured that there are mechanisms in place to ensure timely reporting of suspected violations and to evaluate and implement remedial measures. These tools may also be used to track and identify trends in organizational performance against corrective action plans developed in response to compliance concerns. Regular internal reviews that provide a Board with a snapshot of where the organization is, and where it may be going, in terms of compliance and quality improvement, should produce better compliance results and higher quality services.

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.

Identifying and Auditing Potential Risk Areas

Some regulatory risk areas are common to all health care providers. Compliance in health care requires monitoring of activities that are highly vulnerable to fraud or other violations. Areas of particular interest include referral relationships and arrangements, billing problems (e.g., upcoding, submitting claims for services not rendered and/or medically unnecessary services), privacy breaches, and quality-related events.

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."[17] Audits can pinpoint potential risk factors, identify regulatory or compliance problems, or con¿rm the effectiveness of compliance controls. Audit results that reÀect compliance issues or control de¿ciencies should be accompanied by corrective action plans.[18]

Recent industry trends should also be considered when designing risk assessment plans. Compliance functions tasked with monitoring new areas of risk should take into account the increasing emphasis on quality, industry consolidation, and changes in insurance coverage and reimbursement. New forms of reimbursement (e.g., value-based purchasing, bundling of services for a single payment, and global payments for maintaining and improving the health of individual patients and even entire populations) lead to new incentives and compliance risks. Payment policies that align payment with quality care have placed increasing pressure to conform to recommended quality guidelines and improve quality outcomes. New payment models have also incentivized consolidation among health care providers and more employment and contractual relationships (e.g., between hospitals and physicians). In light of the fact that statutes applicable to provider-physician relationships are very broad, Boards of entities that have ¿nancial relationships with referral sources or recipients should ask how their organizations are reviewing these arrangements for compliance with the physician self-referral (Stark) and anti-kickback laws. There should also be a clear understanding between the Board and management as to how the entity will approach and implement those relationships and what level of risk is acceptable in such arrangements.

Emerging trends in the health care industry to increase transparency can present health care organizations with opportunities and risks. For example, the Government is collecting and publishing data on health outcomes and quality measures (e.g., Centers for Medicare & Medicaid Services (CMS) Quality Compare Measures), Medicare payment data are now publicly available (e.g.,

---

17 See USSG § 8B2.1(b)(5).

18 See USSG § 8B2.1(c).

CMS physician payment data), and the Sunshine Rule[19] offers public access to data on payments from the pharmaceutical and device industries to physicians. Boards should consider all bene¿cial use of this newly available information. For example, Boards may choose to compare accessible data against organizational peers and incorporate national benchmarks when assessing organizational risk and compliance. Also, Boards of organizations that employ physicians should be cognizant of the relationships that exist between their employees and other health care entities and whether those relationships could have an impact on such matters as clinical and research decision-making. Because so much more information is becoming public, Boards may be asked signi¿cant compliance-oriented questions by various stakeholders, including patients, employees, government of¿cials, donors, the media, and whistleblowers.

Encouraging Accountability and Compliance

Compliance is an enterprise-wide responsibility. While audit, compliance, and legal functions serve as advisors, evaluators, identi¿ers, and monitors of risk and compliance, it is the responsibility of the entire organization to execute the compliance program.

Compliance is an enterprise-wide responsiblity.

In an effort to support the concept that compliance is "a way of life," a Board may assess employee performance in promoting and adhering to compliance.[20] An organization may assess individual, department, or facility-level performance or consistency in executing the compliance program. These assessments can then be used to either withhold incentives or to provide bonuses

---

19 See Sunshine Rule, 42 C.F.R. § 403.904, and CMS Open Payments, http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html.

20 Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14,289, 14,298-14,299 (Mar. 16, 2000).

based on compliance and quality outcomes. Some companies have made participation in annual incentive programs contingent on satisfactorily meeting annual compliance goals. Others have instituted employee and executive compensation claw-back/recoupment provisions if compliance metrics are not met. Such approaches mirror Government trends. For example, OIG is increasingly requiring certi¿cations of compliance from managers outside the compliance department. Through a system of de¿ned compliance goals and objectives against which performance may be measured and incentivized, organizations can effectively communicate the message that everyone is ultimately responsible for compliance.

Governing Boards have multiple incentives to build compliance programs that encourage self-identi¿cation of compliance failures and to voluntarily disclose such failures to the Government. For instance, providers enrolled in Medicare or Medicaid are required by statute to report and refund any overpayments under what is called the 60 Day Rule.[21] The 60-Day Rule requires all Medicare and Medicaid participating providers and suppliers to report and refund known overpayments within 60 days from the date the overpayment is "identi¿ed" or within 60 days of the date when any corresponding cost report is due. Failure to follow the 60-Day Rule can result in False Claims Act or civil monetary penalty liability. The ¿nal regulations, when released, should provide additional guidance and clarity as to what it means to "identify" an overpayment.[22] However, as an example, a Board would be well served by asking management about its efforts to develop policies for identifying and returning overpayments. Such an inquiry would inform the Board about how proactive the organization's compliance program may be in correcting and remediating compliance issues.

---

21 42 U.S.C. § 1320a-7k.

22 Medicare Program; Reporting and Returning of Overpayments, 77 Fed. Reg. 9179, 9182 (Feb. 16, 2012) (Under the proposed regulations interpreting this statutory requirement, an overpayment is "identi¿ed" when a person "has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.") disregard or deliberate ignorance of the overpayment."); Medicare Program; Reporting and Returning of Overpayments; Extensions of Timeline for Publication of the Final Rule, 80 Fed. Reg. 8247 (Feb. 17, 2015).

Organizations that discover a violation of law often engage in an internal analysis of the bene¿ts and costs of disclosing—and risks of failing to disclose—such violation to OIG and/or another governmental agency. Organizations that are proactive in self-disclosing issues under OIG's Self-Disclosure Protocol realize certain bene¿ts, such as (1) faster resolution of the case—the average OIG self-disclosure is resolved in less than one year; (2) lower payment—OIG settles most self-disclosure cases for 1.5 times damages rather than for double or treble damages and penalties available under the False Claims Act; and (3) exclusion release as part of settlement with no CIA or other compliance obligations.[23] OIG believes that providers have legal and ethical obligations to disclose known violations of law occurring within their organizations.[24] Boards should ask management how it handles the identi¿cation of probable violations of law, including voluntary self-disclosure of such issues to the Government.

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 con¿dent that raising compliance concerns, questions, or complaints will result in meaningful inquiry without retaliation or retribution. Further, the Board should request and receive suf¿cient information to evaluate the appropriateness of management's responses to identi¿ed violations of the organization's policies or Federal or State laws.

Conclusion

A health care governing Board should make efforts to increase its knowledge of relevant and emerging regulatory risks, the role and functioning of the organization's compliance program in the face of those risks, and the Àow and elevation of reporting of potential issues and problems to

---

23 See OIG, Self-Disclosure Information, http://oig.hhs.gov/compliance/self-disclosure-info.

24 See id., at 2 ("we believe that using the [Self-Disclosure Protocol] may mitigate potential exposure under section 1128J(d) of the Act, 42 U.S.C. 1320a-7k(d).")

senior management. A Board should also encourage a level of compliance accountability across the organization. A Board may ¿nd that not every measure addressed in this document is appropriate for its organization, but every Board is responsible for ensuring that its organization complies with relevant Federal, State, and local laws. The recommendations presented in this document are intended to assist Boards with the performance of those activities that are key to their compliance program oversight responsibilities. Ultimately, compliance efforts are necessary to protect patients and public funds, but the form and manner of such efforts will always be dependent on the organization's individual situation.

Bibliography

Elisabeth Belmont, et al., "Quality in Action: Paradigm for a Hospital Board-Driven Quality Program," 4 Journal of Health & Life Sciences Law. 95, 113 (Feb. 2011).

Larry Gage, Transformational Governance: Best Practices for Public and Nonpro¿t Hospitals and Health Systems, Center for Healthcare Governance (2012).

Tracy E. Miller and Valerie L. Gutmann, "Changing Expectations for Board Oversight of Healthcare Quality: The Emerging Paradigm," 2 Journal of Health & Life Sciences Law (July 2009).

Tracy E. Miller, Board Fiduciary Duty to Oversee Quality: New Challenges, Rising Expectations, 3 NYSBA Health L.J. (Summer/Fall 2012).

Lawrence Prybil, et al., Governance in Nonpro¿t Community Health Systems: An Initial Report on CEO Perspectives, Grant Thornton LLP (Feb. 2008).

Measuring Compliance Program Effectiveness: A Resource Guide

ISSUE DATE: MARCH 27, 2017

HCCA-OIG Compliance Effectiveness Roundtable

Roundtable Meeting: January 17, 2017 | Washington, DC

Measuring Compliance Program Effectiveness – A Resource Guide

HCCA-OIG Compliance Effectiveness Roundtable
Roundtable Meeting: January 17, 2017
Washington DC

Introduction

On January 17, 2017, a group of compliance professionals and staff from the Department of Health and Human Services, Office of Inspector General (OIG) met to discuss ways to measure the effectiveness of compliance programs. The intent of this exercise was to provide a large number of ideas for measuring the various elements of a compliance program. Measuring compliance program effectiveness is recommended by several authorities, including the United States Sentencing Commission (see, Chapter 8 of the United States Sentencing Guidelines). This list will provide measurement options to a wide range of organizations with diverse size, operational complexity, industry sectors, resources, and compliance programs.

During the meeting on January 17, the participants broke into 4 groups of 10 attendees to discuss 2 elements of a compliance program at a time. During four sessions, every participant had a chance to suggest ideas about "what to measure" and "how to measure" with respect to all seven elements of a compliance program. We used the following categories, from the Health Care Compliance Association's *CHC Candidate Handbook: Detailed Content Outline,* as a guide to ensure that all elements of a compliance program were covered:

Compliance Program Elements:

1. Standards, Policies, and Procedures
2. Compliance Program Administration
3. Screening and Evaluation of Employees, Physicians, Vendors and other Agents
4. Communication, Education, and Training on Compliance Issues
5. Monitoring, Auditing, and Internal Reporting Systems
6. Discipline for Non-Compliance
7. Investigations and Remedial Measures

We have listed below many individual compliance program metrics. The purpose of this list is to give health care organizations as many ideas as possible, be broad enough to help any type of organization, and let the organization choose which ones best suit its needs. This is not a "checklist" to be applied wholesale to assess a compliance program. An organization may choose to use only a small number of these in any given year. Using them all or even a large number of these is impractical and not recommended. The utility of any suggested measure listed in

this report will be dependent on the organization's individual needs. Some of these suggestions might be used frequently and others only occasionally. The frequency of use of any measurement should be based on the organization's risk areas, size, resources, industry segment, etc. Each organization's compliance program and effectiveness measurement process will be different. Some may not apply to the organization's environment at all and may not be used.

Any attempt to use this as a standard or a certification is discouraged by those who worked on this project; one size truly does not fit all.

Element 1: Standards, Policies, and Procedures

A. Conduct periodic reviews of policies, procedures, and controls.
B. Consult with legal resources.
C. Verify that appropriate coding policies and procedures exist.
D. Verify that appropriate overpayment policies and procedures exist.
E. Integrate mission, vision, values, and ethical principles with code of conduct
F. Maintain compliance plan and program.
G. Assure that a nonretribution/nonretaliation policy exists.
H. Maintain policies and procedures for internal and external compliance audits.
I. Verify maintenance of a record retention policy.
J. Maintain a code of conduct.
K. Verify maintenance of:

1. A conflict of interest policy
2. Appropriate confidentiality policies
3. Appropriate privacy policies
4. Policies and procedures to address regulatory requirements (e.g., the Emergency Medical Treatment and Labor Act (EMTALA), Clinical Laboratory Improvement Amendments (CLIA), Anti-Kickback, research, labor laws, Stark law).

L. Verify appropriate policies on interactions with other healthcare industry stakeholders (e.g., hospitals/physicians, pharma/device representatives, vendors).
M. Assure policies and procedures address the compliance role in quality of care issues.
N. Verify maintenance of a policy on gifts and gratuities.
O. Verify maintenance of standards of accountability (e.g., incentives, sanctions, disciplinary policies) for employees at all levels.
P. Maintain a Compliance Department operations manual.
Q. Verify maintenance of policies on waivers of co-payments and deductibles.
R. Assure governance policies related to compliance are appropriately maintained.

Source: CHC Candidate Handbook: Detailed Content Outline

Element 1: Standards, Policies, and Procedures		
	What to Measure	**How to Measure**
	Access:	
1.1	Accessibility	• Review link to employee accessible website/intranet that includes the Code of Conduct • Survey - Can you readily access or reference policies and procedures? (Yes/No/Don't know) • Survey - How and where do employees actually access policies and procedures? • Test key word search (searchable) • Audit and interview staff to show policies
1.2	Actual Access	Audit how many actual "hits" on policies and procedures
1.3	Accessible language for code, standards and policies	Flesch Kincaid measuring standard – no more than 10th grade reading level
1.4	Compliance program awareness and communication	• Survey employees to determine the extent to which the code of conduct and other compliance communications are available to employees • Review to ensure the standards, policies, and awareness material is updated and distributed within organization's guidelines
1.5	Impaired or disabled accessibility	Review accessibility options. Look at methods and speak to individuals.
1.6	Policy communication	Communication strategy of policies
1.7	Availability of policy content	Conduct surveys and observation
	Accountability:	
1.8	Accountability	Policy Coordinator designated
1.9	Ownership and accountability of policies	Audit process of how policies get enforced by chain of command when compliance is not the final approver. Is management taking responsibility for implementing and following policies?
1.10	Routine policies and procedures	Confirm that listed owner of each policy and procedure is the actual owner.

	Review/Approval Process:	
1.11	Annual review and Board approval of Compliance Plan	Audit: Review of Board minutes
1.12	Compliance documentation operations manual	Compliance or other oversight committee to review annually to ensure it is up to date.
1.13	Maintenance of policies	Check last review or revision
1.14	Number of policies reviewed and is the review timely	Process review/audit. Use checklist to ensure all basic policy elements are in place, updated consistently and reviewed/approved by appropriate parties.
1.15	Policy approvals	Checklist audit. Create list of policies, review committee and board minutes to ensure all approvals have been obtained.
1.16	Policy review process	Audit process by which policies and procedures are prepared, approved, disseminated, etc.
1.17	Process for ensuring full organizational participation in policy and procedure development	Review documentation/minutes to verify input considered and solicited for policy and procedure development and review
1.18	Process for review and approving	Check for written process
	Quality:	
1.19	Are policies (and procedures) as good as industry practice	Peer reviews
1.20	Integrity of Process for developing and implementing policies and procedures	Audit policy and procedure on policy and procedures
1.21	Language and reading level of policies	Are policies written in plain language, appropriate grade reading level and written in applicable languages for organization? Policy review, Word grade level review and interviews of staff to make sure they understand.
1.22	Language translation	Audit or process review. Are policies and the code of conduct translated into appropriate languages for organization?
1.23	Usefulness	SURVEY - Do department policies and procedures assist you in doing your job effectively? (Yes/No/Don't know)

1.24	Need for policies that don't exist	Interview staff to determine if they need the certain policies to strengthen internal controls.
1.25	Policies and procedures	Request review from external experts
	Assessment:	
1.26	Assessment of all company policies	Check list of policies; which are compliance and which are business
1.27	Essential compliance policies and procedures exist	Can staff actually articulate policies and procedures; test staff
1.28	Existence of procedure to support policy	Audit for procedure to support policy
1.29	Fundamental policies and procedures in place	Have focus groups of work units/departments to determine whether they understand the policies and procedures necessary to do their jobs.
1.30	Identifiability	• Index of policies available and current • Numbered policies, not just titles
1.31	List of policies are applicable to employees	Supervisors to assess direct staff
1.32	Are those affected by policy given the opportunity to weigh in on policy when developed?	Focus groups and interviews of those affected by policy.
1.33	List of required policies	Create checklist to make sure minimum policies are in place and then audit against the list.
1.34	Effectiveness of policies	Effectiveness of policies based on the submission hotline calls
1.35	Policies and procedures that have been identified as part of corrective action	Process review. Conduct annual meeting with compliance and legal to look at databases and control and prioritize review to ensure implementation and ongoing compliance with policies and procedures.
1.36	Policies for high risk and operational areas	Audit
1.37	Policies, standards and procedures are based on assessed risks	Risk assessment, policy exists for each risk identified in the risk assessment (coverage of a specific risk topic)
1.38	Policy inventory to ensure no overlap and contradiction of policies	Create inventory and analyze inventory. Analyze and review past efforts. Look at various departments that might have overlapping policies.
1.39	Policy review following investigation/issue	Top policies implicated in an investigation are reviewed to determine if policy ambiguous, complex, fails to adequately safeguard issues. Validate through audit.

1.40	Routine policies and procedures are addressed and filter down.	Review department and committee agendas to ensure policies are addressed
	Code of Conduct:	
1.41	Code of Conduct	Audit: Review dates, board approvals, distribution processes, attestations, survey employees for understanding, conduct focus groups.
1.42	Compliance program awareness and communication	Survey employees to determine the extent to which they know the content of the Standards of Conduct (SOC) and how to access it.
1.43	Integrate mission, vision, values, and ethical principles with code of conduct	Compare code with mission and vision statements to see if it includes elements/statements. Check to see if code is accessible to employees
1.44	Maintenance of code of conduct	Is code written, posted for employees, documented frequency of reviews, and survey/test employees on ability to locate it
1.45	Distribution	Documentation of Code of Conduct distribution tracking and results over past two years for all employees, employed physicians, allied health professionals, independent (contracted) physicians, volunteers and vendors/contractor/consultants in the organization
1.46	Orientation	Audit to ensure all employees receive orientation to the SOC and compliance policies within 30 days of hire.
1.47	Staff understanding of code of conduct and policies and procedures	• Review test scores after training. • Conduct interviews.
	Updates:	
1.48	Compliance program communication of rule changes	Review periodically and at rule changes – Audit to ensure there is adequate communication to employees, including changes in policy/procedure.
1.49	New and updated policy distribution and education of appropriate staff	Process review - Does organization have formal process to make workforce aware of new policies or changes in policies?
1.50	Practices implemented after new policy	Audit practices and review committee minutes and other documentation to determine how new policies are implemented.
	Understanding:	
1.51	Understanding of Policies/Procedures	• Conduct surveys and/or focus groups on specific policies

		• Audit adherence to policy/procedure
1.52	Orientation	Ensure employees are provided instruction by knowledgeable personnel for questions/clarity
1.53	Policies reflect practice	Use policies as audit tool and then interview, observe and conduct document review to ensure policies are being followed.
1.54	Questions asked by employees	System in place to track employee questions and concerns to ensure consistent guidance. Track departments where questions come from to deploy additional education where necessary.
1.55	Understandable to board and c-suite	Test board and c-suite on location and understanding
1.56	Understandable to employees	• Reading comprehension test • Situational tests • Test of location
	Compliance Plan:	
1.57	Maintain compliance plan and program	Review written plan or written schedule of compliance activities
1.58	Maintain compliance department operations manual	• Audit existence of written manual, handbook, or reference guide • Test whether the manual is current
	Confidentiality Statements:	
1.59	Verify maintenance of appropriate confidentiality policies	• Audit procedure for obtaining confidentiality statements from employees • Audit employee files for signed confidentiality statements from employees
	Enforcement:	
1.60	Compliance with policies	Conduct interviews, observation.
1.61	Policy violations	Audit policy and procedures to make sure practice consistent with policy.
1.62	Adherence to policies and procedures for cases involving patient harm and reporting to regulatory agency	Review policies and procedures and cases involving patient harm and validate proper reporting to regulatory agency

Element 2: Compliance Program Administration

A. Maintain a compliance budget (e.g., contribute to planning, preparing, and monitoring financial resources).
B. Report compliance program activity to the governance board/committee.
C. Coordinate operational aspects of a compliance program with the oversight committee.
D. Collaborate with others to institute best compliance program.
E. Coordinate organizational efforts to maintain a compliance program.
F. Define scope of compliance program consistent with current industry standards.
G. Assure that the compliance oversight committee's goals and functions are outlined.
H. Evaluate the effectiveness of the compliance program on a periodic basis.
I. Maintain knowledge of current regulatory changes and interpretation of laws.
J. Assure the credibility and integrity of the compliance program.
K. Recognize the need for outside expertise.
L. Oversee a compliance education program.
M. Verify the organization has defined the authority of the compliance officer at a high level.
N. Verify the governing board understands its responsibility as it relates to the compliance program and culture.
O. Assure that the role of counsel in the compliance process has been defined.
P. Define the responsibilities, purpose, and function for all compliance staff.
Q. Assure staffing for the compliance program.
R. Verify compliance risk assessments are conducted periodically.
S. Participate in the development of internal controls and systems to mitigate risk.
T. Incorporate relevant aspects of regulatory agencies' focus into compliance operations.
U. Oversee integration of the compliance program into operations.
V. Develop an annual compliance work plan.
W. Demonstrate independence and objectivity in all aspects of compliance program.
X. Maintain an independent reporting structure to the governing body (e.g., Board, Physician Practice Executive Committee).

Source: CHC Candidate Handbook: Detailed Content Outline

Element 2: Compliance Program Administration		
	What to Measure	**How to Measure**
	Board of Directors:	
2.1	Active Board of Directors	• Review minutes of meetings where Compliance Officer reports in-person to the Audit and Compliance Committee of the Board of Directors on a quarterly basis • Conduct inventory of reports given to board and applicable committees.
2.2	Board understanding and oversight of their responsibilities	• Review of training and responsibilities as reflected in meeting minutes and other documents (training materials, newsletters, etc.). Do minutes reflect board's understanding? • Review/audit board education – how often is it conducted? Conduct interviews to assess board understanding.
2.3	Appropriate escalation to oversight body	• Review minutes/checklist in compliance officer files
2.4	Commitment from top	• Review compliance program resources (budget, staff). • Review documentation to ensure staff, board and management are actively involved in the program. • Conduct interviews of board, management and staff.
2.5	Process for escalation and accountability	Process review (document review, interviews, etc.). Is there timely reporting and resolution of matters?
	Compliance Budget:	
2.6	Appropriate oversight of budget	Review charter of governing body (Board) to verify it includes approval of compliance budget
2.7	Budget is based on an assessment of risk and program improvement/effectiveness	Is the Board's approval of the budget based on identified risks and effectiveness evaluation/program improvement?
2.8	Sufficient compliance program resources (budget, staffing)	Review budget and staffing to ensure significant risks are managed appropriately
	Compliance Committees:	

2.9	Active involvement of compliance committee members	Track percentage of attendance of each compliance committee member over the last year
2.10	Assure that the compliance oversight committee goals and functions are outlined	Review charter of committee
2.11	Committee structure	Review documentation of structure of committees as well as charters. Ensure no conflicting charters.
2.12	Compliance committee composition and attendance	Review charter and minutes to assure attendance.
2.13	Cascade administration of compliance program throughout the organization	Different operational areas give some certification/disclosure to the compliance office
2.14	Composition of Compliance Committee	Review organizational chart to validate correct composition
2.15	Effectiveness of compliance committee meetings	Keep executive report card by member qualitative/quantitative with indicators of contribution on topics
2.16	Engagement	In the last two years, have the compliance committee meetings been held in accordance with the charter?
2.17	Engagement of Directors/Managers	Review committee structure to evaluate how directors/managers are participating in Compliance Operational Committee(s) meeting includes agenda, minutes, attendance and reports from subcommittees
2.18	Executive Leadership engaged in Compliance Program	Review frequency of meetings, membership, attendance, agenda and minutes over the past year of the Compliance Executive Committee to include all members of the Senior Executive team receiving information directly from the Compliance Officer
	Accountability:	
2.19	Leadership accountability	Audit documentation and conduct interviews. Some examples might include: • Employee education completion rates • Demonstration of promotion of compliance (e.g., town hall meeting presentations, newsletters, etc.) • Completion of audit or review action items within established time frame
2.20	Management accountability for compliance	Process and document review and interviews. • Is there a mapping of operational or management responsible for championing compliance?

		• Is there a mapping of management responsible for key areas of compliance to ensure accountability? • Does top management support the compliance team?
	Compliance Officer:	
2.21	Competency	• Certification (CHC, CHPC, CHRC) • Annual evaluation, coaching, corrective action, professional development
2.22	Is the compliance officer a key stakeholder in the strategic initiatives of the organization	• Review participation of compliance officer in strategic planning process and due diligence processes.
2.23	Compliance department involvement in enterprise-wide initiatives/entities/strategies (e.g., involvement or penetration in joint venture initiatives and other organizational inventory)	• Process review, including review of organizational chart to ensure compliance captures enterprise-wide entities. • Interviews with compliance and other committees.
2.24	Compliance independence/compliance structure	• Does the reporting structure reflects the "express" authority required? • Audit program charters (compliance program or Audit committee)
2.25	Compliance integration	Audit to determine the extent to which compliance officer is involved in training, policy development, marketing and other operational aspects of the business
2.26	Compliance Officer reporting structure and oversight to ensure direct access to C suite and board	• Document review - Look at organizational chart and conduct interviews. • Review board minutes and documentation that there are regular meetings with CEO and or appropriate parties. • Ensure compliance officer has authority and is comfortable to go to board.
2.27	Compliance officer's independence/objectivity	• Review compliance officer's job description. Does s/he report directly to CEO, board (not CFO or Legal)? Conduct interviews, focused groups, audit. • Seating location of compliance with the business, senior teams are together, and dotted line on org chart • Interview compliance officer to see if they feel they have independence, do they document disagreements, is there executive session for audit committee. • Interview the board, review minutes, and interview the CCO • Review of written organizational structure • Verify the Compliance Officer has the independent authority to retain outside legal counsel • Review if there is screening of compliance officer material to the Board of Directors

		• Regular executive session of the Compliance Officer with the Audit and Compliance Committee of the Board
2.28	Credibility of compliance officer	Job Description review, ongoing training of compliance officer, basic competencies, certifications, reporting structure
2.29	How much authority does the compliance officer have to start a working group to look at changes?	• Have needed changes been made, and if not, why not? • What authority does the compliance officer have and how does he or she exercise it? • Where is the compliance team with regards to identifying working groups to help attack a new compliance risk?
2.30	How supported the compliance officer feels	• Interview compliance officer; • Documentation review.
2.31	Organizational perception of compliance officer and corporate compliance program	Survey employees regarding: • Their perception of the compliance officer role. • Whether they know who the compliance team is, how to get to them and, what to tell them. • Is the compliance staff approachable? • Are the compliance staff solution facilitators or looked at as the organizational police force?
2.32	Compliance problem solving and adequacy of process	Process review
	Staffing:	
2.33	Adequacy of staffing and resources	• FTEs assigned to compliance function • Review compliance matters and if they have been addressed timely. • Review and ensure policies and procedures are implemented and being followed. • Review documentation of reports to committee(s) and board. • Assess status of work plan and any delays. • Ensure documentation of risk assessment. • Review documentation regarding discussions at board level regarding budget. • Review benchmarking data from similar entities.
2.34	Assurance of staffing	Review qualifications of staff; ratio of compliance staff to business, compensation to the business
2.35	Adequacy of compliance staff based on risk assessment	Risk assessment considers the number and competency of staff required to address risk

	Compliance Plan:	
2.36	Compliance plan assessments	• Document review, including compliance plan and policies. • Is there an external review conducted periodically? • What is the role of internal audit with regarding to compliance? • How does internal audit interact with compliance? • Benchmark program with similar sizes within the same industry
2.37	Compliance plan process	Audit process for development of the annual compliance plan.
2.38	Compliance organization	Assess the positioning and effectiveness of the compliance organization staff, titles, organizational chart, pay, promotion records compared to other areas within the organization
2.39	Document that establishes the authority of the program	Document review, meeting minutes for approval.
2.40	Perception of compliance program	Survey employees
	Culture:	
2.41	Accountability	SURVEY - Does the compliance department have an impact on how you do your job? (Yes/No/Don't know)
2.42	Accuracy and Trust in Monitoring	SURVEY: Do you believe the information from your department is reported with a high degree of integrity and accuracy? (Yes/ No/Don't know)
2.43	Culture	Conduct cultural survey (interviews, confidential surveys, focus groups, etc.) and report findings to compliance committee and board. Review minutes to ensure report out and action plan established.
2.44	Effectiveness of compliance program in the field	Survey of field compliance people
2.45	What is company doing to drive compliance culture?	Surveys. • What does company incentivize? • What does the company promote and look down on? • Is compliance program tied to mission, vision, values?
2.46	Employee comments from "Rounding"	Audit the tracking of what employees report when proactively asked by compliance department (or leadership, etc.) and how this information is managed and reported.

2.47	Measuring effectiveness of executive communication on compliance	Track on-line engagement (clicks) and survey audience
	Incentives:	
2.48	Aligning performance management system (promotion system) with ethics and compliance objectives	Audit criteria of promotion, bonuses and assignments
2.49	Compliance and Ethics Role/participation for developing the incentive system	Have an outside independent expert audit the incentive system and compliance officer's participation
2.50	Is incentive system consistent with compliance program	Employee Survey
	Performance Evaluations:	
2.51	Proper alignment of compliance objectives with organizational performance incentives (promotions/performance appraisals/bonuses)	• Audit disciplinary records and performance evaluations for consistency with compliance • Audit/Review of process for performance incentives (promotions/performance appraisals/bonuses) criteria to include compliance components
2.52	"Compliance" as a performance appraisal element	• Audit performance appraisals. Some options include: o Acknowledgment of no disciplinary action o Education completion o Documentation of promotion of compliance • Are merit increases tied to performance? • Does completion of compliance education, promotion of compliance through words, actions or no documented disciplinary action and/or, completion of corrective action plans within the due dates play a role into the calculation of merit increase? • Compliance is part of the annual performance evaluation and HR knows how to evaluate issues for compliance
2.53	Manager performance evaluations	Managers have open door policy, communicate compliance directives/initiatives, address compliance matters and effectiveness is noted in performance evaluation.
2.54	Is compliance taken into account in promotion decisions?	Review promotion lists and documentation to support promotion. Did the individual actively promote compliance?
2.55	Organizational Retaliation	Track whistleblower promotion, bonuses, sick days, disciplinary, corrective action measures and exit interview over long term

	Risk Assessments:	
2.56	Compliance Resource knowledge and competence	Survey, focus groups and interviews
2.57	Compliance staff knowledge of current regulatory changes and laws	Document review and interviews. Review certificates of attendance at conferences/other educational events, "tools" used to keep compliance staff current, compliance budget (to support access to current regulatory changes and laws).
2.58	Monitoring of regulations that impact the organization	Document and process review, interviews. • Is there a policy and procedure? • Is there evidence that regulations, etc. are disseminated and implemented? • Are there designated individual(s) that monitor laws, regulations, policies that impact organization? • How do they get the information and what do they do with it to make sure it gets to the right people?
2.59	Risk Assessment Cycle	• Audit adherence to risk assessment cycle • Annual documented risk assessment has been communicated to oversight committee
2.60	Risk based work plan that covers compliance plan elements with board approval and regular reporting on those projects to board	Compliance Committee and board minutes review.
2.61	Work plan development based on risk assessment	Process and document review.
2.62	Prioritization of risk and consultation with applicable risk partners (i.e., legal, HR, IT, risk management, etc.)	Documentation and process review. Is there a risk based plan? How was it developed?
2.63	Exit interview	Compliance concerns that come up in exit interviews are addressed
	Compliance Work Plan:	
2.64	Compliance work plan	Audit to ensure the work plan is developed and implemented and it is followed-through and outcomes are reported to compliance committee or to governing body

2.65	Effectiveness of compliance program	Written annual work plan that includes minutes
	Legal Counsel's Role:	
2.66	Role of counsel in compliance process	Interview counsel regarding their involvement. • When they are brought into matters? • Where is counsel situated in relation to compliance officer on organizational chart?
2.67	Existence and adherence to policy on involvement of legal in handling matters under privilege	Review policy and sample areas that were referred to legal followed the policy
	Other:	
2.68	Job descriptions of management	Review of management job descriptions. Do managers have concrete compliance deliverables other than training and abiding by Code of Conduct?

Element 3: Screening and Evaluation of Employees, Physicians, Vendors and other Agents

A. Assure organization has processes in place to identify and disclose conflicts of interest.
B. Assure inclusion of compliance obligations in all job descriptions.
C. Assure inclusion of compliance accountabilities as an element of performance evaluation.
D. Verify background/sanction checks are conducted in accordance with applicable rules and laws (e.g., employment, promotions, credentialing).
E. Assure compliance-sensitive exit interviews occur.
F. Monitor government sanction lists for excluded individuals/entities (e.g., OIG, GSA, SDN, SDGT).
G. Verify due diligence is conducted on third parties (e.g., consultants, vendors, acquisitions).
H. Assure corrective action is taken based on background/sanction check findings.

Source: CHC Candidate Handbook: Detailed Content Outline

Element 3: Screening and Evaluation of Employees, Physicians, Vendors and other Agents		
	What to Measure	**How to Measure**
	***Accountability for screening*:**	
3.1	The individual(s) responsible for exclusion screening has clear accountability for the screening function.	• Audit the job description, training material, orientation material, and annual performance evaluation of the individual(s) responsible for exclusion screening to ensure this responsibility is clearly articulated and performance is measured. • Annually review/discuss the exclusion screening process individually with each person responsible for sanction check screening; review the document retention processes to ensure documentation of the screening function, response to findings, and corrective actions are adequately maintained.
	Conflict of Interest:	
3.2	Potential conflicts of interest are disclosed.	Audit the conflict of interest disclosures for completeness and the extent to which those who complete the disclosure information.
3.3	The organization conducts effective education on Conflict of Interest (COI)	• Review training materials and interview staff to determine the effectiveness of the education. • Audit completed attestations or disclosures to ensue individuals are disclosing conflicts according to education provided.
	Employee accountability:	
3.4	The extent to which employees are made aware of compliance expectations.	Conduct focused interviews with employees and audit the performance review process to ensure compliance expectations are well understood and employees are held accountable for these expectations.
3.5	Accountability for compliance is clearly articulated in employee performance evaluations.	Audit performance evaluations to ensure compliance obligations are clearly articulated and performance against these requirements is measured.
3.6	Accountability for compliance is clearly articulated in employee job descriptions.	Audit job descriptions to ensure compliance obligations are clearly articulated.

3.7	Employees are provided education regarding their compliance obligations and they understand these requirements.	• Audit employee education files to ensure education is being provided according to the organizations training plans and/or policies and procedures. • Review post-tests to confirm understanding. • Interview employees to confirm their understanding of their compliance obligations and responsibilities.
	Employee disclosure:	
3.8	The organization has established a policy that requires prospective and current employees, and prospective and current vendors to disclose to the organization if they are or may be excluded.	• Audit and conduct a document review to ensure disclosure requirements are clearly articulated in the policy and disclosures are being made as required. • Conduct a policy review to ensure that that immediate reporting is a requirement for employees and a provision in vendor agreements.
	Employee screening:	
3.9	All employees are screened prior to hire.	Audit human resource files to ensure documentation supports that newly hired employees were screened prior to their first day worked.
3.10	Screening considers other names/alias and States used by a prospective employee.	Review applications for each type of screening (criminal, OIG, SAM, State, SSN, etc.) and audit to determine if screening was completed against other names/states used by the prospective employee.
3.11	The organization has defined which employees, vendors, medical staff, and others will undergo criminal, financial and/or other background checks prior to hire.	• Perform assessment/audit to ensure the organization had identified which individuals receive criminal, financial, Social Security trace, drug screening, or other background checks. • Audit to ensure such background checks are being performed and reviewed prior to employment.
3.12	The organization has defined criteria for review of criminal, financial, and/or other background checks and hiring decision are made based on this established criteria.	Perform assessment/audit to ensure the organization has established criteria to evaluate the acceptability of a candidate based on findings of criminal, financial, or other background check(s) used by the organization.
3.13	Employees are provided education regarding the organization's screening process.	Interview employees and conduct documentation reviews to confirm that employees understand the importance of not letting licenses expire and the effect of exclusion.

3.14	The organization ensures that applicants for employment understand disclosure requirements.	Review employment applications to ensure disclosure is made to prospective employees, including exclusion and background screening requirements, and these screenings are completed.
3.15	The organization has established a policy regarding the frequency of screening.	• Perform a document review to ensure the frequency of screening is being done in accordance with policy. • Audit the screening process to ensure screening is being completed according to policy.
3.16	The organization has established sufficient controls in the hiring process and vendor engagement process to prevent the organization from hiring an ineligible individual or entity.	• Audit, perform document review, interviews staff and vendors, and conduct datamining to determine if sufficient controls are in place to prevent the organization from hiring an "ineligible" individual or entity. • Use data-mining to compare lists of new employees with due diligence lists. • Ensure the vendor master file is updated with vendors that have been screened.
3.17	The organization has established a screening program that is consistent with all laws and regulations.	Conduct a legal review and analysis of screening process to ensure it is being administered in a manner consistent with federal and state laws.
3.18	The organization has established a process to screen employees and other relevant individuals at least monthly.	Audit screening process to ensure screening of employees and other relevant individuals is being conducted at least monthly and according to policy.
3.19	The organization has established a policy and procedure which defines the screening requirements for employees, vendors, medical staff and others. The policies include description of the databases that individuals will be screened against and the frequency of screening.	• Conduct a document review to verify the policy and procedure has been established, is complete, and audit to ensure screening is being conducted consistent with policy. • Perform assessment/audit to ensure organization has identified which lists to check and how often each is checked and the screenings are being checked per policy. • Perform assessment/audit to ensure all relevant types of individuals and entities (employees, temps, vendors, etc.) are being screened per policy.
3.20	The organization has a process to determine when additional screening may be necessary based on findings from compliance investigations. (Relevant event (situational) screening (R.E.S.))	Conduct a review of compliance investigation files to determine if consideration for additional screening is warranted and review the results of additional screening completed as part of the investigation process (situational) when applicable

3.21	The organization has a policy and procedure which articulates the process for screening, investigation of potential "hits," actions taken in response to a positive finding, tracking exclusions, and communication to appropriate stakeholders.	Conduct documentation review and audit to ensure screening is being completed according to policy requirements and that all process elements related to investigation, resolution, tracking, and communication are being managed according to policy requirements.
	Exit Interviews:	
3.22	Employee awareness of organization's compliance program.	Review organization's employee termination process such as exit interviews, surveys, and/or questionnaires to test for employee awareness of the organization's compliance program.
3.23	Employee exit interviews are conducted and employees are asked about the compliance program and any concerns, risks, violations or failures of the compliance program.	• Review organization's employee termination process such as exit interviews, surveys, and/or questionnaires to ensure compliance program questions are incorporated into exit interviews and the exit interviews are reviewed and evaluated. • Audit to ensure all terminated/separating employees have completed an exit interview and that compliance questions are included and evaluated.
3.24	Vendors and other 3rd parties are interviewed at the termination of the engagement and asked about their awareness of the compliance program and any concerns, risks, violations, or failures of the compliance program.	Review organization's vendor termination/off-boarding process such as interviews, surveys, and/or questionnaires to ensure compliance program questions are incorporated into the process and interviews/results are reviewed and evaluated.
3.25	The organization has established a policy and procedure for conducting exit interviews for employees leaving the organization. The exit interview process includes questions related to compliance obligations and any known violations of law, policies, or procedures.	Review policy and procedure to ensure the organization has an established process. Audit exit interview files to ensure interviews are being conducted according to policy. Review to ensure that any identified violations of law, policy or procedure are thoroughly investigated.
	High Risk Screening:	
3.26	The organization has established a policy identifying high risk positions in the organization that may require additional screening.	Conduct policy review to ensure high risk positions (e.g., clinicians working with children or mental health, cash handlers) are identified in policy, and the policy includes a description of any

		additional screening requirements (fingerprinting, financial background checks, etc.). Review employment and vendor files to ensure the additional screening is occurring according to policy.
	Licensure:	
3.27	The organization has a process to ensure that individuals who transfer positions within the organization are appropriately licensed and credentialed for the job they will be performing.	Audit and conduct a document review, audit to ensure a process for examination of licenses and credentials is established for employees transferring positions within the organization. Audit to confirm process is being followed and individuals transferred have appropriate license and credentials for the position they are assuming.
3.28	The organization has established a policy and procedure for licensure and certification reviews, including review upon hire, upon transfer, and during renewal periods.	Perform document review and audit to ensure a policy for verification and review of license and certification, including source verification, exists and licenses and certifications are consistently reviewed according to policy.
	Response to Exclusion:	
3.29	Appropriate action is taken in response to potential and identified exclusion	Audit to ensure refunds are initiated if required and employment, contract, or medical staff action is taken upon discovery (including vendors).
	Response to Screening:	
3.30	The organization takes action on the results of screening.	Perform a document review to ensure screening results are being evaluated and appropriate action is taken where necessary.
3.31	The organization has established a process for investigation and resolution of positive "hits."	Audit process to ensure “hits” are investigated and that false positives are resolved when there is confirmation that the individual does not match the excluded individual.
3.32	The organization has a policy and procedure in place that articulates how potential sanctions will be evaluated and resolved.	Conduct document and process review and audit recent identified sanctions to ensure the evaluation and resolution is consistent with policy.
	Vendor:	
3.33	Vendors and other 3rd parties adequately satisfy compliance obligations	Conduct audit of vendors and other 3rd parties to ensure they have documented evidence of required compliance training, orientation to the organizations Standards of Conduct, orientation to applicable compliance policies and procedures.

3.34	The organization has established a process to ensure vendor and other third party agreements are managed consistent with the terms of the agreement.	Conduct a document review and interviews to ensure there is communication between lawyers who develop the agreements and facility level personnel managing the engagement to make sure it is implemented and being managed according to the terms of the agreement.
3.35	The organization requires vendors and other third parties to certify screening has been completed as required by the agreement.	Audit to determine that vendors respond to request for certification. Review process to determine that actions taken for failure to respond or provide required certifications are consistent with the agreement. Ensure that response to certification is reviewed by an appropriate individual and communicated to facility operations. Audit to ensure that renewal decisions consider compliance with certification requirements.
3.36	The organization has established a policy outlining the compliance obligations of vendors and other third parties (including adherence to the Standards of Conduct). Vendor agreements include the right to audit the vendor to ensure compliance with their obligations.	Conduct document review and perform audits to ensure vendors meet the compliance obligations required.
3.37	The organization has established a policy prohibiting vendors that are excluded from working in the organization.	Audit exclusions to ensure policy is being adhered to.
	Vendor Screening:	
3.38	Vendors and other 3rd parties are adequately screened for exclusion.	• Audit vendor records and cross check to ensure the vendor is adequately screened, in accordance with agreement and/or entity requirements. • Develop checklist of criteria for vendor compliance review and audit against that list for vendor screening requirements. • Survey peer organizations to ensure the organization's vendor and 3rd party screening process is consistent with industry practice.
3.39	The organization has an effective process to review third party vendors.	Audit and conduct a document review to ensure: • Third party contracts allow for organization to review vendor files for compliance with screening requirements.

		• The organization has requested the third party's policy and procedure related to vendor screening of employees. • The organization conducts reviews of third party contracts. • The organization has established a policy on how often screenings are required to be done by the third party. • The organization has established a policy requiring third parties to produce proof that they are checking their employees. • The organization has established a policy establishing which databases third parties are checking, especially regarding practitioners, including geographic specifics (state databases). • The organization has established a process for independent evaluation of what screening the vendor is supplying.
3.40	The organization has requirements, via policy or contractual terms, for screening of first-tier, downstream and related entities (contractors)	Audit to verity evidence that contractors are being screened pursuant to contractual requirements.

Element 4: Communication, Education, and Training on Compliance Issues

A. Disseminate regulatory guidance material.
B. Communicate compliance information throughout the organization.
C. Assure compliance training occurs.
D. Distill complex laws and regulations into a format employees can understand.
E. Assure workforce staff are educated on compliance policies.
F. Assure a mechanism exists to evaluate employee understanding of compliance responsibilities.
G. Promote a culture of compliance throughout the organization.
H. Encourage employees to seek guidance and clarification when in doubt.
I. Participate in continuing education to maintain professional competence.
J. Verify participation in ongoing compliance training programs is tracked.
K. Assure general compliance training is conducted for all employees, physicians, vendors, and other agents.
L. Assure risk-specific training is conducted for targeted employees.
M. Provide HR and management with training to recognize compliance risk associated with employee misconduct.

Source: CHC Candidate Handbook: Detailed Content Outline

Element 4: Communication, Education, and Training on Compliance Issues		
	What to Measure	**How to Measure**
	Training:	
4.1	The organization provides risk area specific training to employees designated to be in high risk positions.	• Audit to ensure the organization has designated the positions deemed to be high risk (coding, billing, physicians, etc.) and established training requirements for these high risk positions. • Compare risks posed by these positions against training materials to ensure specific risks are addressed. • Audit high risk training completion rates.
4.2	The organization has established a compliance training plan. The organization assures that training is completed according to the established plan. The training plan is periodically updated or refreshed.	• Conduct document review to ensure the training plan exists and includes required training, expected audience, topics covered, and method for deployment. • Audit sign-in sheets or other tracking tools to ensure individuals are attending required training. • Review to ensure training plan is periodically updated.
4.3	The organization defines the appropriate audience for each type of compliance training (general, issue specific, high risk, etc.).	• Audit job codes to ensure the correct training has been assigned. • Review job codes to ensure training, including job specific job training is being conducted according to the established training plan.
4.4	The organization offers CEU's, when appropriate, for its compliance education and training.	• Perform a documentation review to determine the extent to which the organization offers CEUs for compliance training. • Evaluate the effect of offering CEUs on training completion rates.
4.5	The organization has established a process, policy and/or procedure to communicate and provide training to employees on new laws, regulations, policies, and procedures.	Conduct a document review to ensure a process for communicating and training employees on new laws, regulations, policies, and procedures has been established and such communication and training is being conducted consistent with the established process.
4.6	The organization has established a policy requiring compliance training and education. The organization	• Conduct a document review to ensure a policy has been established and it is periodically updated.

	regularly updates the education policy and monitors compliance with training requirements.	• Confirm by audit that employees are completing educational requirements according to the policy.
4.7	Compliance education/information is included in all education deployed throughout organization.	Conduct a documentation review to verify that at least one compliance related topic/slide is included in every educational presentation, program, or module deployed throughout the organization.
4.8	The organization bases training for individuals who are designated to be in high-risk positions on a formal process for assessing risk and evaluating control vulnerabilities. The organization develops issue-specific training based on the results of the risk assessment and identified internal control weaknesses.	• Conduct a review of the process the organization has for assessing risk and evaluating control weaknesses. • Review the training plan and training materials to ensure the training addresses those issues that are of significant risk and that the organization may be vulnerable to.
4.9	The organization has created their compliance training program around job families to address specific risks identified within a job family.	• Audit the compliance training program to determine if training is tailored to the risks identified and associated with specific job families. • Audit to ensure training is assigned based on job families.
4.10	The organization evaluates policy and compliance failures and provides re-education to applicable staff.	• Audit files of known policy or compliance failures to ensure re-training is considered as part of corrective action. • Audit to ensure the re-training is completed. • Track for reoccurrences to determine the effectiveness of the re-training and employee understanding.
4.11	The organization tracks disclosure reports (hotline calls, direct contacts to the compliance department) following employee education to determine the extent to which the education was effective at raising employee awareness of specific areas of vulnerability.	• Monitor, audit and review disclosure tracking logs to evaluate the effect of education on disclosures. • Track how employees become aware of issues to analyze the effect training has on employee awareness and reporting.
4.12	The organization maintains documentation of all education provided.	• Conduct document review and audit to ensure all compliance related education is documented, including material covered, attendees, and deployment method. • Audit to ensure documentation of post-training tests is maintained to evaluate employee level of understanding.

4.13	The organizations training plan is regularly updated to address new laws and regulations.	Obtain from counsel list of new laws and regulations and audit against training plan to ensure new laws are adequately addressed.
4.14	The organization has considered the most effective method for compliance education deployment.	• Review the training plan to ensure the organization has considered the most effective method of disseminating training to employees, medical staff, contractors, leadership, Board, and others (on-line, written, in-person, small or large group, etc.). • Audit training records to determine if training has been deployed according to plan.
4.15	The organization has established a formal method for orienting new employees to the compliance program and their obligations and responsibilities.	• Audit to ensure employees have received their compliance orientation consistent with the orientation policy. • Review names, dates and materials used to orient new employees to the compliance program over the past 2 years
4.16	The organization has considered the accessibility of compliance education to individuals with disabilities or language barriers and provides education in various formats to accommodate individuals with disabilities or language barriers.	Survey employees with communication issues or disabilities to ensure the education was accessible and understandable.
4.17	Employees of the organization perceive compliance education as useful and sufficient to address the compliance requirements in their job.	Survey employees to understand their perception of compliance training usefulness and sufficiency.
4.18	The organization has established a method(s) to evaluate the effectiveness of compliance education.	• Conduct document review to determine if the organization has established a method for evaluating the effectiveness of compliance training. • Audit incident logs and hotline reports to evaluate the effect training has had on behavior.
4.19	The organization measures the effectiveness of training though the use of post-training tests or evaluations.	• Conduct document review to evaluate the existence of post-training tests or evaluations. • Review to confirm the results of post-training tests or evaluations are evaluated and tracked. • Review to confirm modifications to training materials considers feedback from post-training tests or evaluations.
4.20	The organization integrates specific risks identified through the risk assessment process into compliance training.	Compare risk assessment to training plan to ensure the high risk issues identified are included in the training plan.

4.21	The organization solicits feedback from employees on compliance training needs. Employee recommendations are included in training modules disseminated.	• Conduct document review to ensure employees surveyed for their training/education needs and what feel they need training on. • Interview staff to assess effectiveness of training plan • Confirm that training considers employee feedback.
4.22	The organization has established a policy regarding the frequency of required compliance training.	Audit training logs to ensure compliance related training is disseminated and completed as required by policy.
4.23	The organization updates compliance training based on new policies, procedures, processes, laws, and regulations.	• Review education update process. • Verify issues identified through the risk assessment, issue tracking system, and other internal and external tracking systems are considered and evaluated as training programs are updated.
4.24	The organization evaluates training effectiveness.	Conduct knowledge survey 6 months after training is deployed.
	Accountability:	
4.25	The organization has established an incentive program that ties, in part, meeting compliance objectives to incentive payments and other perks.	Review performance evaluations to ensure they include compliance elements as part of performance, merit, and incentive review.
4.26	The organization has established mechanisms to ensure that employees are held accountable for their compliance obligations.	• Review job descriptions and performance evaluations for specific compliance metrics. • Review Standards of Conduct and other awareness information to ensure compliance obligations are clearly articulated, including the requirement to report compliance concerns.
4.27	The organization has a mechanism in place to evaluate the extent to which employees understand their compliance responsibilities.	Survey employees to test their understanding of their compliance obligations and responsibilities.
4.28	The organization holds management employees accountable for ensuring their employees understand the Standards of Conduct and compliance related responsibilities	Review department meeting minutes and conduct random staff interviews to determine if first-line managers discuss compliance obligations with their direct reports and that staff understand specific compliance requirements associated with their job.

4.29	The organization has established a policy regarding sanctions for those employees who don't complete required compliance training and sanctions employees according to the established guidelines.	• Document review and audit to ensure a policy exists related to sanctions for failure to complete compliance training. • Audit to ensure policy is being followed as described.
	Awareness:	
4.30	Employees are aware of and understand the organization's compliance program and understand their responsibilities under the program.	Survey employees.
4.31	The organization promotes compliance through activities such as Compliance Awareness Week, Compliance Fairs, or other employee involvement activities.	Review if and how the organization engages in activities designed to promote compliance awareness.
	Board:	
4.32	The organization has established specific compliance competencies for members of the Board Composition and appropriate governing committees.	Perform a document review to ensure sufficient compliance competencies exist within the Board and appropriate governing committee membership.
4.33	The organization has established a formal program to orient new Board members and senior leaders to the compliance program and their obligations and responsibilities.	• Conduct document review to determine if the organization has formalized a compliance orientation program for new executives and new Board members. • Conduct an audit to ensure orientation is provided as required by the orientation policy. • Review names, dates and materials used to orient new members of the Board of Directors and senior leaders to the compliance program over the past 2 years.
4.34	The organization's training plan provides for specific education that will be provided to the Board and senior executives. The plan includes the topics that will be covered, the frequency of training, includes current industry developments and resources, and provides education on their responsibilities for compliance.	Review training materials provided to the Board and senior executives and conduct personal interviews to ensure training is provided pursuant to the plan and the level of understanding of the material presented.

4.35	The organization provides senior leadership and board member compliance education and they adjust strategy and operations in response to the training and other information provided to them.	• Conduct a document review to determine the responses/questions posed by senior leaders and Board members after training. • Evaluate effect of training on the organization's operations and strategy. • Track questions posed by senior leaders and Board members to determine level of understanding of material presented.
	Communication:	
4.36	The organization's performance appraisals and job descriptions include the requirement for employees to promote compliance. Employees at all levels of the organization can and do articulate the compliance/ethics message. There is a requirement that managers insert compliance messages into meetings and other communications with staff.	Perform a document review, conduct employee personal file audits, and interview or survey employees to ensure the organization's compliance program, including expectations and responsibilities are formally and informally communicated to the employee population.
4.37	A compliance program communication plan is developed and implemented.	• Review the organization's communication plan to ensure the plan addresses key messaging for employees. • Conduct focus group discussions and survey employees on the effectiveness of this messaging.
4.38	The compliance department/staff regularly present compliance program information and updates at staff meetings, other department meetings, board meetings, town halls, and other forums.	• Conduct a document review to ensure the compliance department/staff regularly provide updates to the organization and is a visible presence at various meetings. • Confirm the organization documents and tracks all such presentations.
4.39	The organization requires compliance representatives to be present at every senior management and governance-level meeting.	• Conduct a documentation review to verify there is an expectation for compliance to be represented at all senior management and governance-level meeting. • Confirm by audit that a compliance representative has attended all such meetings.
4.40	The organization provides compliance information, training, and updates in a manner that is understandable for employees (reading level, languages, case studies, verbal communication)	• Survey employees to determine the effectiveness and level of understanding by employees to the material presented. • Conduct post-training evaluations. • Review and track questions and disclosures made following the dissemination of information and education.

4.41	The organization ensures there is adequate two-way communication between the compliance department staff and employees such as periodic check-ins with employees and follow-up with employees who report concerns.	Survey employees to determine: • their perception of how accessible the compliance staff is, • if they know to report concerns, and • if they believe their concerns are taken seriously and are adequately addressed.
	Competency:	
4.42	The organization has defined the competencies required for the compliance staff including requirements for certification or other specific skills/expertise.	Review job descriptions and personnel files for all compliance staff to ensure specific compliance competencies and certification requirements are designated and the staff possess the required competencies/certifications.
4.43	The organization requires all compliance staff to maintain their competency by attending appropriate educational sessions.	• Conduct a documentation review to verify that requirements for compliance staff education, including professional development, are established. • Audit to verify that compliance staff attend education as required. • Review compliance department budget to ensure sufficient resources are devoted to providing appropriate education (including conferences) to the compliance staff.
4.44	The organization provides focused education to compliance staff members to ensure they are competent in evaluating and investigating issues.	• Conduct document review to evaluate the education provided to compliance staff. • Review to ensure compliance staff being trained on conducting internal investigations, audits, performing risk assessments, vulnerability analysis, etc.
4.45	Development plan for compliance staff	Review documentation of development plan and monitor to ensure that plan requirements are completed annually or as otherwise specified in the plan
	Culture:	
4.46	The organization has established a culture of compliance.	• Survey all employees to determine the extent to which employees believe there is a culture of compliance in the organization and employee understanding of the compliance culture. • Review the organization's compliance training material to determine if scenario based training and/or other interactive training methods are used to promote understanding.
	Incentives:	

4.47	The organization has established methods for rewarding and recognizing employees for compliance activities.	Review incentive, rewards, and recognitions programs to ensure successful achievement of compliance metrics are considered when recognizing and rewarding employees and leadership.
	Vendors and Volunteers:	
4.48	The organization has established the training requirements for vendors.	• Conduct document review to ensure the organization has established training requirements for vendors. • Review files to ensure vendors have completed training as required. • Conduct site visits to review vendor employee completion of required education.
4.49	The organization has established the compliance training requirements for volunteers.	• Conduct document review to ensure the organization has established training requirements for volunteers. • Review files to ensure volunteers have completed training as required.

Element 5: Monitoring, Auditing, and Internal Reporting Systems

A. Protect anonymity and confidentiality within legal and practical limits.
B. Publicize the reporting system to all workforce members, vendors, and agents.
C. Assure monitoring occurs for violations of laws and regulations.
D. Conduct organizational risk assessments.
E. Develop work plan based on risk assessment.
F. Maintain reporting system(s) to enable employees to report any noncompliance (e.g., hotline).
G. Respond to compliance concerns expressed by employees through internal reporting.
H. Assure the existence of procedures for monitoring adherence to compliance policies and procedures.
I. Conduct compliance audits.
J. Analyze compliance audit results (e.g., track, trend, benchmark).
K. Develop an annual compliance audit plan.
L. Evaluate results of audits conducted by external entities.
M. Monitor that retaliation for reporting compliance concerns has not occurred.
N. Recognize need for attorney consultation in the auditing/monitoring process.
O. Employ auditing methodologies that are objective and independent.
P. Determine sampling methodology consistent with circumstances.
Q. Assure a timely response is made to reported compliance concerns.

R. Monitor management's implementation of corrective action plans.
S. Provide timely feedback to management on compliance concerns based on audit results.

Source: CHC Candidate Handbook: Detailed Content Outline

Element 5: Monitoring, Auditing, and Internal Reporting Systems		
	What to Measure	**How to Measure**
	Reporting System:	
5.1	Accessibility of reporting system	Interviews. Surveys. Ask employees and managers if the reporting system is accessible to them. Is it available in languages that are most spoken in the organization?
5.2	Adherence to 60-day overpayment rule	Review incident tracker; ensure days to open or days to close do not exceed that timeframe. Track efforts to identify; status benchmarks specific days to completion.
5.3	Trust in the system	Survey - Do you feel you can freely report ethics and compliance issues without fear of retaliation from managers? (Yes/No/Don't Know).
5.4	Reporting and Investigation Process	Review external benchmarking reports (# of calls, time it takes to close cases, anonymous, etc.).
5.5	Reporting system – compliance response to reporters	Document review. Focused groups and speaking with employees about hotline. • Are calls made through reporting system responsive to reporters? • Are policies followed regarding the response to reports received? • Are reports responded to on regular intervals and updated appropriately?
5.6	Reporting System: Hotline/Direct contacts	Document review, audit. • Are hotline calls or matters brought to the attention of the compliance department (direct contacts) categorized, trended, and reported to the compliance committee and board level committee? • Are there tracking, trending and reporting of how these matters have been resolved?
5.7	Reporting to compliance (hotline, report to the compliance officers, etc.)	Reports reflect communication methods (call, anonymous, email, direct, etc.)?

5.8	Thoroughness of investigation files	Review 5 investigation files for summary of issue, interviews conducted and summary of interviews, investigation summary and results/conclusion and corrective action (as applicable).
5.9	Time to respond to incident report	Review date reported, date responded, date investigation closed.
5.10	Promotion of reporting system	Documentation review. Interviews, visual walk-throughs. • Are hotline posters hanging in conspicuous areas? • Interview staff – do they know how to report? • Audit use of reporting system (how frequently is it used)? Consider internal or external reporting benchmarks.
5.11	Published reporting system	Survey. • Is there a hotline, compliance officer? • How to report? • How to find information?
5.12	Demonstration of a formal compliance program	Document review. Is there identification of prioritization of key compliance indicators; reporting and escalating to compliance oversight committee?
5.13	Documentation to support resolution of reported matters.	Audit. Document review.
5.14	Effectiveness of compliance department	Document review, surveys, interviews, focus groups. • Is there a report card on associates' comfort level? • Do they know who to go to with concerns? • Do they know whom to trust? • Is there follow-through? • What is the trust and integrity around members of compliance department?
5.15	Discipline for non-compliance	Document review, interviews. Monitor to ensure discipline policies are followed.
5.16	Effectiveness of Follow-up to Compliance Concerns	Interview/survey caller for satisfaction with follow-up of concern.
5.17	Culture Survey	Document review, assessment of responses. Do culture surveys include questions such as: • Do you know how to report concerns? • Are you willing to report concerns?

		• Do you trust that concerns will be addressed fairly when reported?
5.18	Awareness and effectiveness of internal reporting system	Review system use. Look to make sure employees, vendors, contractors can report; gauge the level of retaliation; individual comfort of reporting systems; survey. Conduct interviews.
5.19	Awareness of the discipline	Survey.
5.20	Hotline reporting system/vendor	Monitor. • Are test calls of the system conducted? • Are the calls answered? • If external vendor, are they following the organization's documented notification protocol?
5.21	Internal reporting from business partners, contractors, etc.	Contract review and interviews. • Is compliance department aware of the contracts with business partners, contractors, etc.? • Is there an inventory of partners? • Do they know how to contact compliance department with issues?
5.22	Investigation resolution and timeliness	Documentation review. • Are reports closed timely? • Are there completion notes and dates matters and submitted to board?
5.23	Presence of Internal Reporting System	Review policies and procedures and mechanisms for internal reporting. Are matters being reported according to policy? What should be reported up in regards to compliance? Check to see if it has been reported up appropriately.
5.24	Process of how a concern is handled	Review documentation that reflects this process; audit case files to demonstrate this decision process was followed. Is it a management issue, legal issue, other? Is there a triage tree?
5.25	Subordinate conduct	Interviews. Document reviews. Does organization measure whether line managers are monitoring the conduct of their subordinates?
5.26	Written escalation process	Documentation review. Is there a written procedure to determine at what point a matter must be reported to the board, committee, or government agency?
	Risk Assessments:	
5.27	Risk Assessment	Documentation/process review. • Is there a documented enterprise-wide risk assessment?

		• What is the work plan creation process? • Is internal audit included? • Is a fraud risk assessment conducted? • Is this information used as a basis for creating the auditing and monitoring plan or work plan?
5.28	Risk Assessment Process	Process map of risk assessment process. • Who participates? • How are topics prioritized? • What is the process? • How are mitigation steps determined? • Is education provided? • How are the results reported?
5.29	Risk based work/audit plan	Document review. Is the compliance work/audit plan based on a documented risk assessment and is it risk based?
5.30	Follow-up to Risk Assessment	Review process for findings of risk assessment and whether implemented; audit or monitor implementation; audit and monitor as necessary after implementation to mitigate risk (closing the loop).
5.31	Frequency of risk assessment, scope and coverage and tools used for risk assessment	Audit the risk assessment process for these areas.
5.32	Information flow from business units to compliance department for the risk assessment process	Interviews.
5.33	Internal audit department's relationship with compliance department	Document review, interviews. • Is risk assessment utilized to create annual audit plan? • Who participates in the risk assessment? • Are there routine interactions between compliance and internal audit? • How many internal audit hours are designated for compliance related work? • Or, how are audits delegated to internal audit or compliance after risk assessment is completed?
5.34	Is auditing and monitoring based on risk areas identified in risk assessment process	Review risk assessment process and what audits and monitoring are on work plans.

5.35	Monitoring effectiveness	Document review. Is the monitoring plan linked to risk assessments to make sure highest risk areas are covered?
5.36	Participation of business leadership in risk resolution	Verify that risk reporting is going to business leadership; routine inclusion of risks at compliance committee; assessment of effective follow-up when risk resolution is off-track.
	Monitoring and Auditing Work Plan:	
5.37	Method to create audit plan	Document/process review. • What internally and externally are used to create the risk based plan? • Is a review of submitted corrective action plans included in the review and planning process?
5.38	Audit and monitoring based on risk assessment	Document review comparison of audit/monitoring plan.
5.39	Approval process of work plans	Review minutes of Board and Compliance Committee meetings.
5.40	Auditing and monitoring process	Document and process review. How is annual work plan developed? Who is responsible for it?
5.41	Are there sufficient audits conducted?	Documentation review. Look at audit plan, including "ad hoc" audits that were unplanned, but conducted in response to a matter.
5.42	Audit inventory	Document review. Is there an inventory of all audits being conducted either by internal staff or external consultants in the organization?
5.43	Compliance department role in establishing audit plan	Review of audit plan and process to ensure compliance is key stakeholder and part of the process.
5.44	Defined process to hire outside experts to conduct audit/investigation and review	Review policy and procedures and interview decision makers on the process and criteria to trigger the hiring of outside experts to conduct audit/investigation and review.
5.45	Completion rate for compliance work plan	Audit or document review. • Were the items on the work plan completed by the due date? • If not, do compliance committee and board level committee minutes reflect discussion about this? • If work plan was changed, is there compliance committee and board committee documentation to support this?

5.46	Periodic reviews of monitoring and auditing plan	Document review. Is monitoring and auditing plan reviewed periodically at the compliance committee and board level committee to make sure it is still fit for purpose and focused on high-risk areas for the organization?
5.47	Random auditing is conducted to identify unknown risks	Portion of the audit plan is based on random selection.
5.48	Effectiveness of gift policy and procedure	Survey on gift policy awareness and audit gift registry or system for compliance with P&P.
	Audit Process:	
5.49	The need for the advice of counsel related to audits	Review of referral process to track attorney referral. Is organization tracking that attorney is consulted when audit findings note issues?
5.50	Validate the organization is conducting audits	Process review.
5.51	Audit results and actions in response to audit is reported to the governing body	Review of minutes.
5.52	Audit results are part of performance reports and/or incentives	Documentation review.
5.53	Authority to initiate audit	Document review. Interviews. Audit. • Is there documentation outlining who is authorized to initiate an audit, including the engagement of outside consultants? • How is this done? • How thorough is it?
5.54	Audit process	Process review. Documentation review. Are audits defined with issue, scope, objectives, and resources?
5.55	Accountability	Create audit reports for compliance audits identifying purpose, scope, sample selection (if applicable), findings, conclusion, and recommendations.
5.56	Audit benchmarks	Audit of audits for benchmarking - Are the audit findings actionable?
5.57	Compliance audit results	Process review and document review. • Are audit results being analyzed, tracked, trended and reported? • For example, how often are education or policies and procedure changes needed? • Is management (not compliance) responsible for corrective action plans?

		• Is compliance monitoring corrective action plans to completion and then conducting follow-up audits to ensure the actions remain in place?
5.58	Meaningfulness of audits	Review of audit tool.
5.59	Report results	Documentation review. • How is resolution of deficiency documented? • How does the department document? How does the department track what was accomplished (metric: spreadsheet - database)?
5.60	Reporting of audit results	Process review. Documentation review. • Are audit results are reported to operations? • Compliance Committee? • Governing body?
	Corrective Action Plans:	
5.61	Depth and breadth of root cause analysis	Audit and interview process to determine if proper depth and breadth of root cause of concern and proper incorporation into corrective action plan.
5.62	Accountability of corrective action	Review agendas, minutes and reports to compliance committee on corrective action plans.
5.63	Action plans in response to an audit finding	Audit of audits to ensure action plans are documented.
5.64	Are identified refunds tracked, documented and returned timely?	Audit and review of documentation to ensure check went out.
5.65	Audit and investigation trending	Validation reviews of corrective action plans. Are audit and investigation findings tracked for trends? Root cause analysis? Fix for entire system?
5.66	Corrective Action Plans	Document review. Audit. • Is there a documented follow up process to make sure management has completed items in corrective action plans? • Were the corrective actions successful in correcting the deficiency? • Are follow up audits conducted to ensure corrective actions do not lapse?
5.67	Reporting of untimely corrective actions	Validation audits/follow-up audits. If there are un-timely corrective actions, are they reported to the compliance committee and governing body?
5.68	Timely corrective actions (new safeguards/controls)	Audit to ensure audits have corrective action documented in a timely fashion.

	Auditors:	
5.69	Auditing the auditors	Hire third party to audit auditors or individual contributors; validate audit results.
5.70	Auditors develop audit instructions	Document review. Are there guidelines in place?
5.71	Auditors skill set and competency to audit the issue	Review audit work product, personnel files, etc.
5.72	Independence	Audit for Independence - Review to ensure no vested interest in outcomes, meet independence requirement as defined by yellow book.
5.73	Process to evaluate auditor skill set to ensure the right audit resources are selected (internal audit, outside auditor, etc.)	Review of auditor background and skill set.
5.74	Standardization of audit process - auditors approach audits in the same way	Audit review to monitor for consistency.
	Non-Retaliation:	
5.75	Monitoring for retaliation	Exit interviews/employee surveys.
5.76	Retaliation	Surveys, focus groups, individual questioning, exit interviews.
	Vendor oversight:	
5.77	Vendor oversight	• Review vendor certifications; track consequences for vendors not adhering to compliance program. • Ensure all vendor contracts include consistent compliance language.

Element 6: Discipline for Non-Compliance

A. Recommend disciplinary action when noncompliance is substantiated.
B. Promote discipline proportionate to violation.
C. Promote discipline consistent with policies and procedures.
D. Verify that discipline is enforced consistently throughout all levels of the organization.
E. Monitor for consistent documentation of disciplinary action.
F. Recommend action for individuals and entities that have been excluded from government programs.
G. Verify that compliance-related violations are addressed in disciplinary policies.
H. Coordinate with management that timely disciplinary action is taken.
I. Verify that disciplinary action is reported to regulatory body when required.

Source: CHC Candidate Handbook: Detailed Content Outline

Element 6: Discipline for Non-Compliance		
	What to Measure	**How to Measure**
	Consistency:	
6.1	Fairness and consistency in disciplinary process	Sample – audit. • Is the disciplinary action policy consistently followed? • Does the compliance committee review and measure fairness and consistency in policy application? • Audit discipline personnel files – consider creating predefined discipline matrices and audit against these. • Interview on perception of discipline applied, survey on perception. • Is disciplinary action in proportion to matter? • Is there consistency for similar matters?
6.2	Approach to determining type of disciplinary action	Review of P&P. • Auditing/testing to determine whether there is a common approach to analyzing the discipline aspect of resolution. • Are there steps embedded into protocol?

6.3	Compliance officer input into disciplinary action decisions	Interview CCO, outcomes review, and audit. Are compliance officer's recommendations taken seriously?
6.4	Decision-making parties	• Audit personnel files. • Policy review. • Is there a disciplinary action committee approach to review results of investigation and previous actions and to make decisions? • Are the appropriate parties (e.g. Legal, HR, Compliance, etc.) part of discipline action decision-making process?
6.5	Thoroughness of disciplinary P&P	Review criteria of including compliance violations and well-defined sanctions for consistent application of disciplinary policies.
6.6	Timeliness of disciplinary action	HR audit of files. Is timely discipline and action carried out?
	Awareness:	
6.7	Understanding	Survey - Is poor performance on compliance responsibilities grounds for disciplinary action?
6.8	Accuracy	Verifying that person completed the compliance expectations that were attested to.
6.9	Compliance goals	Documentation review. Is there consideration of compliance activities in daily activities? Review performance evaluations- Were goals accomplished?
6.10	Compliance incentives	Process review; interviews of leadership and staff interviews. What is the role of compliance when it is implemented?
6.11	Incentive policy	Document review, interviews, and focus groups. • Does the organization distribute badges for centers, or departments for participation in compliance training? • Are there contests for compliance training and publishing of test scores?
6.12	Distinction between disciplinary action and non-retaliation	Interviews, reviews of policies, etc. Assess the effectiveness of the organizational distinction between discipline and non-retaliation and make sure there are appropriate protections regarding non-retaliation.

6.13	Education to ensure employees know expectations	Audit communications regarding expectations and discipline possible. Compare policy and Standards of Conduct to ensure they are clear regarding disciplinary action.
6.14	Employee awareness of disciplinary action policy	Interviews, surveys, etc. Do employees understand there are discipline consequences for non-compliance?
6.15	Employee, vendor, contractor knowledge of code of conduct and their compliance responsibilities	Audit documentation. • Do employees, vendors, and contractors know their responsibilities regarding code of conduct? • Do they sign annual attestations?
6.16	Transparency regarding lessons learned	Document review. Are the lessons learned from disciplinary action conveyed and used as an educational tool for organization?
6.17	Culture	Survey - Do you feel employees who engage in improper work-related activities will be caught?
6.18	Non-retaliation for good faith reporting	Review demotions, terminations and conduct employee surveys.
6.19	Proactive education on violation and discipline	Review policy and procedure and education and training
6.20	Recognition and appreciation	Focus groups, interviews. • Are there recognition and appreciation programs that do not include incentivizing with money? • For example, are there newsletters, reports to governing body, website announcements to recognize those for exhibiting compliance and ethical behaviors and actions?
	Documentation:	
6.21	Discipline transparency	Documentation review. Are high-level results from disciplinary action published (e.g., # of terminations, # of counseling, # of suspensions, and # of corrective action plans)?
6.22	Oversight	Review minutes for number of disciplinary actions for compliance and HIPAA violations in last year reported to the Compliance Committee (dashboard)
6.23	Adequate documentation	Review/audit disciplinary files for supporting documentation of disciplinary action.
6.24	Compliance in business plans	Document, process review. • Is there a leadership scorecard that includes compliance metrics? • Are there compliance incentives built into business plans?

6.25	Notification of licensing boards	HR file audit - before issue is closed, is documentation present and included in tracking system?
6.26	Policy	Document review. Audit. Is there a documented policy addressing discipline for non-compliance?
6.27	Policy exceptions	File review of exceptions. Are exceptions tracked, documented, and evaluated? Who gets to make the decision regarding exceptions? Is this process documented?
6.28	Reporting to regulatory authorities	Audit. Document review. • Look at criteria for reporting and timeliness achieved. • Audit cases and track. • Ensure timely reporting to regulatory authorities of potential violations and discipline to demonstrate organization's commitment to compliance.
6.29	Scope and inclusion of disciplinary action pertaining to the culture	Investigate breadth of discipline and inclusion, audit disciplinary files, and conduct interview. Does discipline include those who know about it and didn't report it or caused it to happen but did not actually do it?
6.30	Scope of disciplinary action	Audit to verify - Are there disciplinary actions/consequences for not reporting?
6.31	System allows for documentation of compliance issues	Document/System review. Does HR system have mechanism for recording and tracking compliance offenses?
	Promotion Criteria:	
6.32	Promotion Criteria	Review if compliance considerations were included in promotion process and criteria.
6.33	Senior executive performance reviews	Process, document review. • Before promotion, does compliance conduct interview to identify or discuss compliance issues? • Does head of compliance participate in the reviews of senior executives? • Is there talk about compliance initiatives with regards to senior executive performance reviews?
6.34	Performance reviews	Document review. • Is there recognition of compliance efforts in performance reviews? • Is compliance built into the performance evaluation for rewarding employees and disciplinary action?

Element 7: Investigations and Remedial Measures

A. Communicate noncompliance through appropriate channels.
B. Assure development of corrective action plans in response to noncompliance.
C. Monitor the effectiveness of corrective action plans in response to noncompliance.
D. Assure remedial efforts are implemented to reduce risk.
E. Cooperate with government inquiries and investigations.
F. Investigate matters related to noncompliance in a fair, objective, and discrete manner.
G. Assure records are maintained on compliance investigations.
H. Participate in negotiation with regulatory agencies.
I. Assure that overpayments to payers are refunded in a timely manner.
J. Collaborate with legal counsel regarding voluntary disclosures.
K. Coordinate investigations to preserve privileges, as applicable.
L. Facilitate independent investigations when necessary.
M. Recommend modification of corrective action plans.
N. Recognize need for subject matter experts.
O. Assure documents relevant to an investigation are preserved.
P. Assure investigation personnel have the necessary skill sets.
Q. Institute immediate measures as necessary to mitigate ongoing harm.
R. Recommend measures to address substantiated incidence of retaliation.

Source: CHC Candidate Handbook: Detailed Content Outline

Element 7: Investigations and Remedial Measures		
	What to Measure	**How to Measure**
	***Guidelines for Conducting an Investigation*:**	
7.1	The organization has guidelines established to ensure thorough, credible, and complete investigations are done in a consistent manner	Review guidelines, policy and procedure and/or protocol on conducting an investigation.
7.2	Effectiveness of investigative process	Review process for common steps to embed into a protocol. Conduct a baseline review to understand what the mandatory parts of the investigation framework are and what may change due to situation or circumstance. • Is the overall investigation process driven by a policy and procedure, subject matter resource involvement, objective reviewer? • Is the process transparent (not everything placed under attorney client privilege)? • Is there a documented investigations process or procedure? • Are investigations being conducted consistent with written procedures? • Is there something that triggers a sentinel event, immediate reporting, the need for external consultants or attorneys? • What is the approval process? • What are timelines with regards to 60-day rule? • Is there a centralized process for keeping up with all investigations in process? • How much flexibility due to situation or circumstances is appropriate and how much needs to be controlled? • Next year, is the process tightened up going forward?
7.3	Individual accountability as part of investigative plan.	Audit. Document review. Interviews. • Is there a baseline investigative plan that outlines communication plan for interviewing current or prior employees? • Does the investigative process include special attention to individual accountability? • Is there investigative mapping and outline to ask questions about who may be in the loop so compliance can be sure they are not part of reporting group? • Are there appropriate protections for people being interviewed and the representation of organization?

		• Is there documentation that the individual is not given assurances that there are no repercussions for him/her?
7.4	Type of documentation required for remedial measures and investigation	Review policies and procedures on record retention and types of documentation
	***Content of Investigation Files*:**	
7.5	Assure records are maintained on investigation	Audit to ask: • Is there a policy and procedure for documentation that needs to be maintained? • Do investigative files match the policy requirements (determine what should be in the attorney file versus the investigation file)?
7.6	Quality of the documentation	Assess whether the who, what, when and how is answered in every investigation; sample log entries
7.7	Assure documents relevant to an investigation are preserved	Read written policy and procedure for investigation records; read investigation files of HR, compliance, and/or legal to confirm compliance with retention period
	Quality and Consistency of Investigations:	
7.8	Quality and effectiveness of investigations	Audit investigations to look at: • quality of questions asked and content considered, involved parties, and report out of findings; • did they involve the appropriate parts of the organization; • are they broad enough; and • did they use internal or external auditors?
7.9	Thoroughness, timeliness and consistency of investigation process among investigators	Audit investigation files
7.10	Triage process	• Audit process to review whether allegations were appropriately and timely handled • Dry run, test, mock report
7.11	Consistency of Investigations	Multiple anonymous (mock) reports on different issues to test process

7.12	Credibility of investigation and remediation process to third parties	Demonstrating it by mock presentation (devil's advocate) - role playing what a regulator might ask regarding the investigation and remediation process.
	Tracking and Trending Investigations	
7.13	Investigation categorization process and trending	Documentation review and audit tracking system. Are investigations being categorized so they can be tracked, trended and reported to compliance committee, senior management and board?
7.14	Retaining documentation of investigations in records management system (tracking, trending, review)	Review of documentation in system
7.15	Documenting when issue is substantiated or not and reporting/trending	Review reports/process
7.16	Compliance log (log and track investigations)	• Does a log exist; • Does it have investigations and actions taken; and • Are there supporting files for each entry so that they can be reported on (HR, Billing) to report the trends?
	Escalation of Investigations	
7.17	Ensure adequate and timely escalation of investigation outcomes	Audit sample of investigation files
7.18	Significant investigations are reported to the governing body	Review board minutes, review policies related to board reporting requirements.
7.19	Investigation reporting to senior leadership and board	Document review, interviews. Are investigations being reported to senior leadership and the board?
	Communication of Investigation Outcomes	
7.20	The appropriate communication of the investigation outcomes (education)	• Conduct an assessment at the conclusion of an investigation of additional communication to the organization for organizational learning and culture of compliance • Document review of meeting minutes and/or interim reports. Were investigations results reported to senior leadership and board? How were the results communicated?

		• Review how results of internal investigations are shared with the organization's governing body, leadership and relevant departments.
7.21	Culture	Survey for whether employees believe that management and/or the compliance officer follows up on reports of compliance concerns and takes appropriate action whenever necessary? (Yes/No/Don't know)
7.22	Perception of investigation results by employees and stakeholders	Focus groups or survey of employees
7.23	Communicate noncompliance through appropriate channels	Read workgroup meeting minutes or emails to determine distribution list includes appropriate individuals (stakeholders, decision makers)
	Training of Investigators	
7.24	Staff who conduct internal investigations have the education necessary to conduct investigations	Peer review on similar organizations. Review of certifications and education provided.
7.25	Number of employees with appropriate certifications that are conducting investigations	Review list of investigators and their certifications
7.26	Investigators have the skill set	Interview investigators and look at work product for facts
7.27	Training/competency of investigators	• Evaluate training transcripts, train them on investigation techniques; • Review the type of training anyone conducting investigations has received over the past 2 years
	Professionalism and Competency of investigators	
7.28	Ensuring investigators are conducting investigation in professional and respectful manner	Interview subjects
7.29	Professionalism and effectiveness of investigators	Conduct and observe mock interviews
7.30	Strength and credibility of investigation process	Role play of investigation process
7.31	Investigate matters in a fair matter, objective and discreet manner	Peer benchmarking to evaluate: • the time it should take to conduct an investigation;

		• what peers do to make sure investigations occur discreetly and timely
	Independence of investigator	
7.32	Objectivity of investigator	Interviews by external source with goal to ensure no internal organizational pressure on the investigators that is improper.
7.33	Assessing uniformity of using outside contractors and experts in the investigation process	Review policies and procedures and audit files for compliance
7.34	Independence and Objectivity of Investigation	Review policies and procedures, survey employee perception, quality control process, etc.
7.35	Independence of investigation (no intimidation is occurring)	Work product and interviews; quality of process (avoid reporting structure conflicts of interest; direct-report)
	Involvement of Legal Counsel	
7.36	Coordinating investigations to protect privilege when necessary	Audit against policies and procedures to determine appropriate attachment of privilege
7.37	Collaborating with legal	• Look at work product to determine quality; • Ensure compliance leads the investigation (unless investigation is being conducted under privilege); • Interview compliance officer and legal counsel to determine the level of collaboration.
	Timeliness of Response	
7.38	Are immediate actions taken immediately	Audit investigation outcomes to see if timely
7.39	Compliance officer authority	Interviews, document reviews. If concern is raised and it is harmful, management needs ability to react immediately even if it is before investigation is complete. Does the compliance officer have the ability and authority to stop an action (e.g., billing)?
7.40	Time to investigation closure	• Track timeliness against benchmark established by organization; • Documentation review. Is length to close investigations being documented, tracked, trended and reported?

		• Are resolution actions (e.g., education, new policy/procedure, corrective action plan, disclosure, repayment, etc.) being documented, tracked, trended and reported?
7.41	Timely processing of refunds, self-disclosures	Audit, monitor, document review of investigations that resulted in refunds, disclosures to ensure they were processed in a timely fashion.
7.42	Self-Disclosure guidelines	Document review, interviews. • Are there written guidelines for self-disclosures? • Do they address members impacted, information to be shared with regulators?
	Corrective Action Plans / Remedial Measures	
7.43	Business leaders are accountable for follow-up to investigations	• Verification that investigative report is shared with those responsible for follow-up. • Closure reports are provided to Compliance Committee. • Audit post investigation to ensure resolution is maintained.
7.44	Effectiveness of corrective actions	Documentation review of corrective actions timeframes met, issues closed out, effective resolution.
7.45	Structure	Review how corrective action plans are created
7.46	Validate that corrective action plans are appropriate, implemented and effective	Review 3 corrective action plans to ensure identified all issues and conduct validation visits
7.47	Accountability	• Review how corrective action plans are tracked; • Review how corrective action plans are reported to Compliance Executive Committee
7.48	Ensure remedial measure for like findings are consistently implemented	Audit
7.49	Measuring sufficiency of corrective action plans that are developed	Sample cases that were substantiated and review the corresponding corrective action plans to ensure they respond to issues identified in internal and external audits and investigations
7.50	Remedial actions - Appropriate remedial action occurred	Review investigation documentation, PowerPoint, training attestation is in the file.

7.51	Ensure remedial efforts are established to reduce risk	Based on the outcome of the investigation; deficiency was fixed, evidence it was fixed, there are other items to review (ex. Charge master) look at the downstream impact - employees, systemic issues (beyond disciplinary action)
	Root cause analysis	
7.52	Conduct root cause analysis to determine if findings need to be addressed in other parts of the organization	Audit documentation
7.53	Resolution of investigations	Audit. Was root cause resolved?
7.54	Accountability/Structure	Obtain a list of ad hoc committees formed around specific compliance issue over the last 2 years
	Adherence to non-retaliation policy	
7.55	Monitoring how the reporter feels about having reported	Interview
7.56	Ensure confidentiality of investigation process	Survey or focused groups, interview participants in investigations
7.57	Exit interview process queries for retaliation	Review of exit interview process
7.58	Culture: Retaliation	Surveys, interviews, exit interviews. • Is there a policy statement in new employee orientation? • Are there communications? • Do employees know how to report potential instances? • Does the organization conduct culture surveys? • Is there a policy statement regarding no obstruction of investigation?
7.59	Adherence to non-retaliation policy	Survey participates in investigation to determine if they felt or feared retaliation
7.60	Substantiated retaliation	Audit
	Government Inquiries/Investigations	

7.61	Cooperate with government inquiries/investigations	• Audit credit received for cooperation; • Read records that contain government correspondence with entity. Review and confirm appropriate responses were submitted on or before requested date.
7.62	Strategic relationship with regulators	Interviews. • Is there a focused approach to building relationships with regulators? • Does staff seek out regulators at conferences, etc. to build relationships?
7.63	Mock presentations	Documentation review. Interviews. • Does the organization conduct mock presentations (e.g., in-house attorney "acts" as government entity? • Compliance presents a discipline part of compliance program to in-house attorney for his/her review and comment.)
	Monitoring Results	
7.64	Validation that investigations are complete	• Auditing, documentation review, interviews after investigations are complete. • Is there a documented (3-6-9 months) timing interval to assess whether "action has traction?" • Is there a process to go back and prioritize or verify that plans or work units are following through on recommended actions?
7.65	Review of investigations in future work planning	• Documentation review. • Is there an analysis of investigations to help inform future work plans?
7.66	Long term effectiveness of remedial measures	Audit - one year of remedial measures where active monitoring ended 6 months prior to validate that remediation still in place
7.67	How larger lessons can be conveyed to the organization	CO could review annually the reports to the board or broader communications to the entire organization; review education on trends and themes.
	Awareness of Investigation Process	
7.68	Education on investigations process	• Audit, monitor training records and educational content. • Is training regarding the investigations process provided at hire and ongoing so employees know what to expect regarding the investigations process?
7.69	Strategic relationship with risk partners (i.e., Legal, HR, risk management, etc.)	Interview risk partners to determine interaction, involvement, knowledge.

	Contract Provisions regarding Investigations	
7.70	Third party and non-employed clinician contracts to ensure they have an obligation to cooperate in investigations.	• Contract review. • Inventory of agreements with 3rd parties and non-employed clinicians to make sure they understand their obligation to cooperate with investigations.
7.71	Inventory of requirements in contracts	Audit. Document review. Are there standard terms that must be included in contracts? A template can be used to ensure all requirements are in contracts.