

Compliance Program Description

Approval by the Providence Audit and Compliance Board Committee

NOTE: The web version of the Compliance Program Description includes internal links that will not function for external parties.

June 5, 2024

Table of Contents

Book 1: Implementing written policies, procedures, and standards of conduct	5
Policy Management Office	6
Policy Approval Process	7
Maintenance of Active Policies	7
Code of Conduct	8
Conflicts of Interest	10
Conflicts of Interest in Research	11
Research and Clinical Trials	12
Gifts, Gratuities, and Business Courtesies	13
Record Accuracy and Retention	13
Fraud, Waste and Abuse and False Claims	14
Referrals	15
Antitrust	15
Emergency Medical Treatment and Labor Act	16
Privacy and Information Security	16
Patient and Member Information and Privacy	17
Patient and Resident Rights	18
Notice of Privacy Practices	
Notice of Nondiscrimination and Communication Assistance	18
Quality of Care and Patient Safety Program	19
Government Inquiries and Investigations	19
Emergency Preparedness and Incident Response	20
Physician Compliance Services	20
Compliance Committee of the California Medical Foundations Board	22
Physician Contracting	22
Pharmacy Compliance Services	22
Laboratory Compliance Services	23
Global Compliance	23
Global Third-Party Due Diligence and Management	24
Key Policies and Foundational Materials	24
Book 2: Designating a compliance officer and compliance committee	25
Providence Compliance Program Core Elements	26
Providence Board Resolution to Affirm the Compliance Program	26
The Chief Compliance Officer	27
Compliance Department	28

Providence Council Structure	28
Third-Party Management	31
Mergers & Acquisitions	33
Key Policies and Foundational Materials	34
Book 3: Conducting effective training and education	35
Patient and Member Information and Privacy	
Board and Senior Leader Education	40
Regulatory Guidance	41
Key Policies and Foundational Materials	41
Book 4: Developing effective lines of communication	42
Open Lines of Communication	42
Integrity Hotline	43
Retaliation Will Not Be Tolerated	44
Key Policies and Foundational Materials	44
Book 5: Conducting internal monitoring and auditing	45
Compliance Auditing and Monitoring	46
Internal Audit	47
Revenue Cycle Compliance	49
Research Billing Compliance	52
Excluded Individuals & Entities	53
Exclusion Screening	54
Proactive Privacy Monitoring Program Overview	55
Key Policies and Foundational Materials	56
Book 6: Enforcing standards through well-publicized disciplinary guidelines	57
Corrective Action	58
Corrective Action Plans	58
Enforcement of Compliance Policies	58
Levels of Violations	58
Key Policies and Foundational Materials	59
Book 7: Responding promptly to detected offenses and undertaking corrective action	60
Investigation Process	60
Corrective Actions	61
Documentation	62
Key Policies and Foundational Materials	62
Book 8: Ongoing risk assessment	63
Work Plan Development	64
Key Policies and Foundational Materials	66

Appendix A: Key Policies Supporting the Program	67
Appendix B: Key Foundational Materials Supporting the Program	69

[Remainder of Page Left Intentionally Blank]

Book 1: Implementing written policies, procedures, and standards of conduct

The OIG <u>General Compliance Program Guidance</u> states: generally, health care entities instruct their employees, contractors, and medical staff on certain duties and any standard parameters around the performance of such duties through policies and procedures. More specifically, through written policies and procedures, entities can provide a roadmap for relevant individuals, outlining their duties within the organization, developing workflow management, imposing documentation requirements, defining individual and organizational oversight roles, and implementing controls entity-wide to mitigate compliance risks specific to the entity. Policies and procedures also demonstrate to stakeholders and other interested parties, including Government regulators, how the entity strives to comply with applicable laws, regulations, and requirements.

A code of conduct and compliance policies are critical elements of any compliance program. The compliance program should also require that all the entity's policies and procedures incorporate a culture of compliance into its day-to-day operations. The code of conduct and compliance policies and procedures should be developed under the direction and supervision of the compliance officer and the Compliance Committee and should be made available to all relevant individuals within the organization.

At Providence we believe that the organization's written policies and standards should take into consideration the regulatory exposure for specific business lines, functional areas, or operational departments across our family of organizations.

The purpose of compliance policies and standards is to establish bright line rules that help caregivers carry out their job functions in a manner that ensures compliance with Federal health care program requirements and furthers the mission and objective of the organization itself. A clear statement of detailed and substantive policies and procedures and the periodic evaluation of their effectiveness is at the core of the compliance program. Policies and procedures are written to address identified risk areas for the organization. Compliance policies and standards are developed under the direction and supervision of the Chief Compliance Officer, vetted through the various compliance committees, and, at a minimum, are provided to all individuals who are affected by the policy at issue, including the organization's agents and independent contractors.

When conducting a review of our written policies and procedures, some of the following factors may be considered as appropriate to the policy or standard under review:

- Are policies and standards clearly written, relevant to day-to-day responsibilities, readily available to those who need them, and re-evaluated on a regular basis?
- Does the organization monitor staff compliance with internal policies and procedures?
- Have the standards of conduct been distributed to all directors, officers, managers, employees, contractors, and medical and clinical staff members?
- Has the organization developed a risk assessment tool, which is re-evaluated on a regular basis, to assess and identify weaknesses and risks in operations?
- Does the risk assessment tool include an evaluation of Federal health care program requirements, as well as other publications, such as the OIG's work plan, special advisory bulletins, and special fraud alerts?

Providence is committed to legal, regulatory, and ethical compliance in its health care services and supporting operations. The purpose of developing and maintaining a comprehensive set of policies and procedures is to provide standards by which Providence business is conducted in accordance with all appropriate legal, ethical, and industry standards and expectations of the persons served.

Our system-wide policies and standards are clearly written, relevant to day-to-day responsibilities, readily available to those who need them, and re-evaluated on a regular basis. Written policies and procedures govern practices at all Providence entities and are available to workforce members. The procedures include steps to comply with federal and state legal mandates, Providence Board policies, and systemwide compliance policies.

The Providence Compliance Program (the "Program") establishes the necessary policies, Code of Conduct (the "Code"), and processes to manage conflicts of interest and exclusion screenings, as appropriate, for our workforce members. The Providence workforce includes caregivers, volunteers, trainees, interns, apprentices, students, independent contractors, vendors, and all other individuals working in the ministries, whether they are paid by or under the direct control of the ministry or are employees of affiliated organizations. In addition, the Code of Conduct, conflict of interest policies, and exclusion screenings apply to the Board of Trustee members.

Policy Management Office

Providence's policy process for system-wide policies is managed by the Policy Management Office (PMO), which is embedded within the Compliance department. The PMO provides direction and oversight for the development, approval, revision, and implementation of all system-wide policies. Subject matter experts and individual divisions are responsible for development and implementation of the various specific policies.

System-wide policies address specific legal and regulatory requirements needed in the course of business. The significance of these requirements generally requires a consistent and standardized approach across the entire organization. Systemwide policies serve as the internal organizational rules that direct our workforce members to conduct themselves in a manner consistent with requirements and expectations.

The PMO develops and maintains the standard practices for adopting and maintaining a system-wide policy; criteria for determining if a policy is a governance or management policy; and the procedures for implementation of policies. This process is outlined in the policy, Creation of System-Wide Policies (<u>PSJH-CPP-731</u>). Currently, System-wide policies, including the related requirements, exist at three levels: Governance Policies, Management Policies, and Technical Standards.

- A *Governance Policy* is a high-level directive or statement of corporate purpose to establish matters of mission, strategic, operation, legal or financial importance to Providence. It is adopted by the Board of Providence and signed by the President/CEO.
- A *Management Policy* is a specific directive mandating certain rules for operation of Providence. These policies are adopted at the senior level of management through the Providence Executive Council and signed by the President/CEO.
- **Technical Standards** are specific action steps and protocols that are required to implement policies in some instances. They are not considered to be policies and are maintained by the appropriate department or division. *Technical Standards* are subject to the same review and approval process as the policies they support.

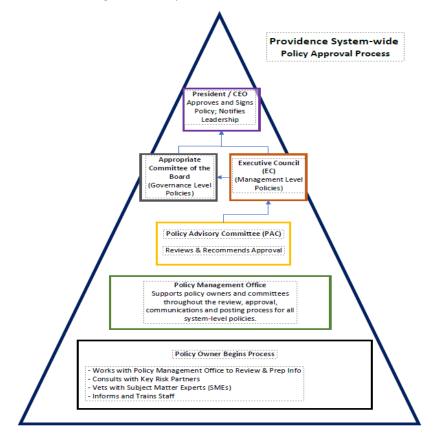
Policy Approval Process

The workflow for policy approval is facilitated by the PMO. The first step in the policy approval process is vetting and approval by the local business lines, subject matter stakeholders, and senior leadership of the business lines including the executive sponsor for the policy. This vetting by Providence leadership and management ensures that policies and procedures do not create undue pressure to pursue profit over compliance.

The second step is vetting and approval by the Policy Advisory Committee (PAC). The PAC is a chartered committee comprised of representatives from various operational senior leaders. The meetings are facilitated by the PMO. The PAC provides strategic guidance and oversight to assure system-wide policies are conducted in accordance with applicable federal, state, and local laws and regulations.

PAC members are responsible for carefully reviewing the proposed policies, proposing policy edits as appropriate, and recommending or denying a final draft to move forward to the Executive Council (Management Level Policies) or the appropriate committee of the Board (Governance Level Policies). The PAC generally meets on a monthly cadence.

The third, and last step, is review by the Executive Committee of Providence with final approval by the Providence CEO or in the case of governance policies the Board of Trustees.



Maintenance of Active Policies

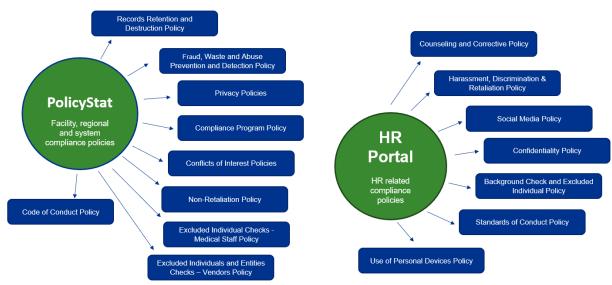
Policies are developed as appropriate, and there is an ongoing review and revision process of all system-wide policies managed by the PMO on a regular basis. System-wide policies are reviewed annually with a thorough high-level review, update, and approval every five years. Generally, procedures are written by the organization's regions, facilities, and service lines to operationalize these policies. However, when appropriate, the Program may define the parameters for

implementation of a policy. Regional and ministry level policies are created, maintained, and reviewed in a manner consistent with system-wide policies.

Providence's policies are maintained on a web-based platform, currently <u>PolicyStat</u>[®]. This platform provides a centralized location for policy management, and a consistent method for historical policy document retention.

The PolicyStat[®] platform contains system-wide policies, as well as ministry and region-specific policies. It is a platform that is accessible to all workforce members on their workstations. The ability to conduct a search of the PolicyStat database allows workforce members to locate policies quickly and easily to complete their work in a compliant and ethical manner.

Additionally, Human Resources also maintains caregiver related polices on the Caregiver Service Portal. These policies are ministry/entity specific. Refer to the <u>Caregiver Service Portal</u> for the most up-to-date version of these ministry specific policies.



Policies and Where to Find Them (not an exhaustive listing)

Code of Conduct

The code of conduct is an important tool to communicate an organization's mission, goals, and ethical requirements central to its operations. The code articulates the entity's commitment to comply with all Federal and State laws and regulations. It defines the entity's ethical standards necessary to fulfill its mission and govern the conduct of its officers, employees, contractors, medical staff, and others who work with or on behalf of the organization.

As appropriate, the OIG strongly encourages the participation and involvement of the organization's board of directors, officers (including the chief executive officer (CEO)), members of senior management, representatives from the medical and clinical staffs, and other personnel from various levels of the organizational structure in the development of all aspects of the compliance program, especially the code of conduct. Management and caregiver involvement in this process communicates a strong and explicit commitment by management to foster compliance with applicable Federal health care program requirements. It also communicates the need for all directors, officers, managers, employees, contractors, and medical and clinical staff members to comply with the organization's code of conduct and policies and procedures. Unlike the more detailed entity-wide policies and procedures,

the code of conduct is brief, easily readable, and covers general principles applicable to all members of the organization.

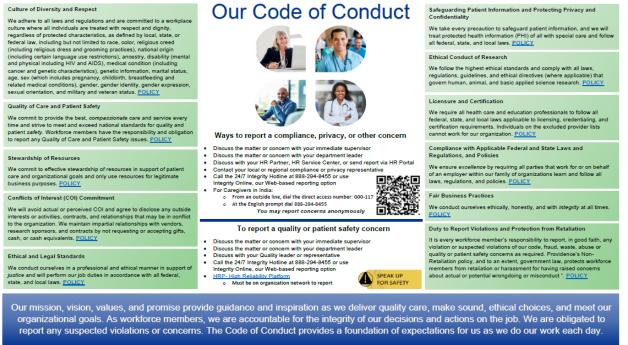
The development of a Code of Conduct (the "Code") and associated policy is the responsibility of Compliance. The <u>Code of Conduct policy</u> (PSJH-CPP-722) and the <u>Code</u> are approved by the Board of Trustees and is an indication of our leadership's focus on the culture of compliance that they support within the organization. The purpose of the Code is to define and encourage behaviors in support of Providence's mission, vision, and values and to prevent and halt unethical or unlawful behavior as soon as reasonably possible after discovery. The Code of Conduct policy addresses the expectations of the organization for personal and professional standards of conduct and the acceptable, ethical behaviors of all workforce members.

The Code is distributed to all workforce members and is made available to other appropriate groups, including contractors and vendors, either in paper form or by internet and intranet connections. The <u>Providence Code of Conduct</u> is posted on our public facing website in various languages.

The Code of Conduct policy and the Code are essential components of the Compliance Program and together establish the expectation that all workforce members and others, who are acting on behalf of Providence, will comply with the standards established. There is also an expectation that everyone contracting with Providence will adhere to our Code of Conduct policy and Code.

The Code is supplemented by policies, procedures, guidelines, and standards directed to specific areas of operations. Unlike the more detailed policies and procedures, the Code is brief, easily readable, and covers general principles applicable to all members of the organization. Other documents on policies and procedures may also be published at various organizational levels.

Doing the Right Thing Right



A copy of the code of conduct can be found <u>here</u>.

Underlying the Code is the expectation that all Providence workforce members and our agents are

required to:

- Uphold ethical principles in the workplace;
- Share responsibility and accountability for keeping the organization in compliance with applicable laws, regulations and policies governing business practices; and
- Understand their obligation to promptly report concerns about improper or inappropriate actions without fear of retaliation.

The Code is provided to newly hired workforce members in electronic and paper formats. Education is provided annually to workforce members, reinforcing the expectations provided in the Code of Conduct policy and Code. Electronic copies of the Code of Conduct are readily available to workforce members and can be found on the public-facing website, an internal intranet site, and attached to the Code of Conduct policy. Additionally, Providence has translated the Code into Spanish, Russian, Vietnamese, Ukrainian, Tagalog, and Hindi to be inclusive of its diverse workforce.

In addition to the Code, other documents, such as the policies within human resources and Medical Staff Bylaws, are published at various levels of the organization. Healthcare practitioners privileged at any of our facilities are governed by the facilities' respective Medical Staff Bylaws and must follow them. These bylaws provide a process for resolving ethical and compliance issues related to the practice of medicine within our organization. All human resource policies are maintained by Providence's Human Resources Division.

Additionally, Providence Human Resources maintains a Standards of Conduct policy on the <u>Caregiver</u> <u>Service Portal</u> to inform workforce members of the expected standards while working for a Providence entity or on its premises.

Workforce members who commit compliance or privacy violations will be investigated and recommended for sanctions based on the level of the violation, as prescribed by policies. The level of violation will be determined by management with consultation and guidance from Human Resources according to the severity of the violation, whether the violation was intentional or unintentional, the impact or influence of the event on the patient, the risk impact to Providence, and/or whether the violation indicates a pattern or practice of violations.

Other mitigating and escalating factors may be considered as determined by the core leader in conjunction with Human Resources and Compliance. Any sanction imposed on workforce members will be in accordance with the level of violation and applicable Human Resources policies.

The Program, the Department of Legal Affairs (DLA), and other appropriate departments provide supplementary compliance guidance on legal and regulatory compliance through publication of periodic regulatory memoranda and guidelines. Coordination, review, and consultation with the PMO in Compliance is conducted when appropriate and needed.

Conflicts of Interest

Providence maintains two separate <u>conflicts of interest policies</u> designed to support our Code of Conduct, culture of compliance, and to meet Internal Revenue Service and other regulatory requirements for maintaining independence in decision making by our workforce members and agents. The first, <u>PSJH-GOV-208</u> Conflicts of Interest, is a governance level policy and applies broadly to: Providence board members (governing, community, and foundation); Providence executives; health care administrators; department heads; school administrators; director-level core leaders with hiring and/or contracting authority; employed physicians; purchasing agents/buyers; and other physicians with whom Providence has a significant relationship such as non-employed medical directors; and supply chain and pharmacy

resource council members. The second, <u>PSJH-CPP-724</u> Conflicts of Interest in Research, is a management level policy specific to those performing approved research in a Providence facility.

Additionally, Providence has established a system-wide Ventures Conflict of Interest (<u>PSJH-GOV-220</u>) policy. The purpose of this policy is to establish Providence standards and responsibilities for ensuring that investment and related purchasing activities are conducted free from undue influence or the perception of such influence.

All workforce members are required by policy and the Code of Conduct to report any possible conflicts of interest. In addition, key executives, and caregivers are required to complete an annual Conflict of Interest disclosure. The annual disclosure process is facilitated using a platform that allows for electronic submission of the disclosure, although a paper version is also available.

All workforce members are required to disclose potential conflicts of interest using the <u>Click eCOI</u>[®] platform, when they arise, even if the workforce member is not typically included in the annual disclosure process. Education on conflicts of interest is provided during new hire orientation and to all existing caregivers through the annual Compliance, Privacy and Security Education.

Disclosures that indicate potential or actual conflicts of interest are reviewed and overseen by the Chief Compliance Officer. The Department of Legal Affairs is consulted along with management as needed. When applicable, a conflict of interest management plan is developed to address identified conflicts. Significant conflicts of interest, should they arise, are discussed with management by the Chief Compliance Officer and the Deputy General Counsel, as needed.



Conflicts of Interest (COI) Governance Policy Required Disclosures of Actual, Perceived or Potential Conflicts

Conflicts of Interest in Research

The Conflicts of Interest in Research (COIR) policy, <u>PSJH-CPP-724</u>, outlines who should be submitting the COIR disclosures. All individuals conducting research at Providence should read this policy to confirm if it applies to them. If there are any questions, these individuals should reach out to the Compliance Office at: <u>riscomplianceservices@providence.org</u>.

The required individuals should be submitting their COIR disclosures within 30 days of a new conflict arising or change in existing conflict. All disclosures are to be submitted in the <u>Click eIRB</u>[®] platform. If a new account needs to be created, the reporting individual must reach out to the Compliance Office at: <u>riscomplianceservices@providence.org</u>. Once the disclosure is submitted, the Conflicts of Interest in Research Committee (COIRC) will review the disclosure.

The COIRC meets once a month to review all the disclosures submitted. The Regional representatives are invited to these meetings to share additional information as needed and to weigh in on the review for their regions' disclosures.

- The COIRC determines whether a standard management plan is required (i.e., disclosure of conflict in consent form/publications/presentations), or
- The COIRC determines whether a more detailed management plan is required based on the conflict reported; this is determined on case-by-case basis.

The Research Compliance team will publish management plans in the <u>Click eIRB</u>[®] platform per COIRC decision and a notification will be sent to the reporting individual that the management plan is published.

The reporting individual will review the management plan.

- If in agreement, the reporting individual will sign the management plan to attest they agree to adhere to the management plan.
- If the reporting individual has further questions or disagrees with the assigned management plan, the reporting individual will send a written communication to Research Compliance providing additional information on the reported conflict and request a re-evaluation by the COIRC.

Periodic COIR activity reports will be sent to regional leadership notifying them of the disclosures submitted and management plans published for their region. There are also regional representatives who have read only access to the <u>Click eIRB</u>[®] platform so that they can stay up to date with the disclosure activity in their region.

- The Regional leaders will monitor the implementation of and adherence to assigned management plans.
- For any questions or concerns, they will reach out to the Research Compliance team via <u>riscomplianceservices@providence.org</u>.

The Human Research Protection Program (HRPP)/Institutional Review Board (IRB) have access to the Click IRB[®] platform to view both disclosures and management plans. This team will review the disclosures and corresponding management plans, if applicable, during each IRB submission and consecutive continuing submissions for all key personnel participating in the research study.

Lastly, Research Compliance will perform a review of disclosures within the <u>Click eIRB</u>[®] platform as compared to the Open Payments database for the previous year (Open Payments posts updated information in June for the previous year).

Research and Clinical Trials

Providence physicians and professional staff follow the highest ethical standards and comply with all laws, regulations, guidelines, and ethical directives that govern human, animal, basic science, and applied science research. Research Compliance participates with other organizations responsible for protecting human subjects, investigators, sponsors, and research participants. Providence ministries maintain and communicate accurate information regarding research projects, and submit true, accurate, and complete costs related to research grants.

Providence does not engage in research misconduct, which includes activities such as falsifying results, failing to deal appropriately with investigator or institutional conflicts of interest, and proceeding without Institutional Review Board (IRB) approval or failing to follow the approved IRB protocols. The top priority is to fully inform and protect those patients who are enrolled as human subjects and to respect their rights during research, investigation, and clinical trials.

Providence promotes research consistent with its values of providing services with concern for the

responsible stewardship of resources. Such research must also be consistent with Catholic moral principles.

Gifts, Gratuities, and Business Courtesies

Providence maintains a Gifts, Gratuities and Business Courtesies policy (<u>PSJH-CPP-719</u>) this policy establishes guidelines for accepting and giving gifts, gratuities, and business courtesies, to ensure compliance with regulatory requirements. This policy applies to <u>all</u> caregivers at <u>all</u> levels in <u>all</u> functions and to <u>any</u> third party with whom Providence conducts business.

Providence workforce members may not solicit or accept personal gifts, business courtesies or services from patients, visitors, vendors/suppliers, or business associates, as doing so may be an actual or perceived conflict of interest. Unsolicited gifts of nominal value, as described within this policy, may be permissible under certain circumstances. Gifts that are intended to influence or may be reasonably perceived as having the potential to influence, an individual in the scope of their duties or responsibilities at Providence are prohibited regardless of whether the gift is from present or potential interested parties. Accepting gifts and offers of entertainment creates a risk that judgment and decisions can be influenced. In some cases, acceptance of gifts and entertainment may be considered a violation of federal and/or state laws.

Providence's reputation is based on its commitment to integrity in the delivery of quality patient care and other services. For this reason, Providence workforce members are expected to keep relationships with patients and their family members, students and their families, vendors, non-employed physicians, and their offices and other third parties impartial, and avoid accepting gifts or other items of value including, but not limited to:

- Meals
 Discounts or free services
- Tickets to events Tips and gratuities
- Special favors or loans Paid travel for spouses

Cash or cash equivalents, such as gift certificates or gift cards, may **only** be accepted when given to a member of the workforce by Providence or a fellow member of the workforce. Gift certificates and gift cards are taxable income regardless of their cash value when paid for by Providence. Workforce members may never accept cash or cash equivalents from anyone outside of Providence for activities related to their work at Providence. Workforce members may direct anyone offering a gift to a Providence Foundation.

Any gift, regardless of value, may not be accepted if the gift is given to a caregiver/employee in an attempt to influence their behavior or decision-making. For more details regarding excepting gifts, please refer to the <u>gifts frequently asked question</u> (FAQ) document. The purpose of the FAQs is to provide workforce members consistent guidance on giving and receiving of gifts while fulfilling the Providence St. Joseph Health mission.

Providence maintains a Gift Acceptance policy (<u>PSJH-MISS-150</u>). The purpose of this policy is to adopt and implement policies and procedures that in compliance with federal and state laws delineate actions required relative to fundraising activities and issues arising out of such. Further, the purpose is to implement the Gift Acceptance Policy Statement (the "Policy Statement") which shall pertain to all Providence St. Joseph Health Foundations.

Record Accuracy and Retention

Providence has established a Records Retention and Disposal policy (<u>PSJH-CPP-715</u>) co-owned by Compliance and Enterprise Information Services to support the appropriate retention, protection,

maintenance, and disposition of all records, regardless of their format or media. The policy outlines the requirements for management of data and records, including storage, retention, and disposal, for all known format and media types.

At Providence, we prepare and maintain accurate and complete documents and records. We do this to comply with regulatory and legal requirements, and to support our business practices and actions.

At Providence, we do not alter or falsify records, and do not destroy records to deny governmental authorities access to information that may be relevant to a government investigation.

The Providence Records Retention and Disposal policy (<u>PSJH-CPP-715</u>) provides minimum retention periods for records based on legal, business, and risk management considerations. Where statutory and regulatory record retention requirements conflict, records will be retained for the longest period specified in the applicable statute or regulation.

Providence entities may establish local policies, consistent with and built upon the System policy, to define how records are maintained, stored, and destroyed.

Records related to the Compliance Program are maintained by the Compliance department in accordance with the Providence Records Retention and Disposal policy and shall be made available for inspection as requested to appropriate parties.

Fraud, Waste and Abuse and False Claims

A compliance program can only be truly effective at accomplishing its goal of preventing and detecting fraud, waste, and abuse when the program, its infrastructure, and the work the program does are oriented around the organization's risk profile. The Chief Compliance Officer understands this and prioritizes the organization's risk profile to build an effective and efficient Compliance Program and annual work plan that includes reviewing risk areas around fraud, waste, and abuse.

The services provided by Providence are governed by a variety of federal and state laws and regulations. These laws and regulations cover subjects such as false claims, illegal patient referrals, providing medically unnecessary services, violations of Medicare's Conditions of Participation and submitting inaccurate cost reports. Providence is committed to full compliance with these laws and regulations.

Providence has established an system-wide <u>Fraud</u>, <u>Waste and Abuse Prevention and Detection policy</u> (<u>PSJH-CPP-711</u>). This policy confirms Providence's commitment to prevent and detect fraud, waste, and abuse (FWA) by providing workforce members detailed information regarding: (1) the federal False Claims Act; (2) federal laws and penalties pertaining to reporting and returning overpayments; (3) state laws and penalties pertaining to false claims; and (4) whistleblower protections under certain laws.

Providence monitors and audits compliance with coding, documentation, billing requirements, and cost reporting to detect errors, inaccuracies and improper payments or claims. Providence will take appropriate actions to correct any billing or claims inaccuracies, and to adjust, repay or collect overpayments by government payers and others as identified through the auditing process. Additionally, Providence conducts periodic reviews of its billing and coding practices and for development or refinement of policies and procedures to reduce or eliminate potential risk.

Providence expects that those who create and file claims for payment to Medicare, Medicaid and other payers will file claims that are accurate, complete, and represent the services provided. Billing for clinical trials will follow clinical trial billing protocols and will be submitted in accordance with federal requirements.

The following principles guide our compliance:

- Charges will be submitted only for services or supplies that are provided to the patient/resident and are accurately and completely documented in the medical record or other supporting documentation.
- Charges will accurately represent the level of service provided to the patient/resident.
- Only those services that are medically necessary and are supported by valid orders will be submitted for payment to Medicare, Medicaid, and other payers.
- Under no circumstances will charges or codes be purposely selected to improperly increase the level of payment received.
- Overpayments will be reported and refunded as required by law.
- Cost reports will be accurate and filed in a timely manner.

Providence complies with state and federal False Claims Act requirements. We provide information on our expectations and the FWA policy to our workforce members and contractors. Providence expects that workforce members and contractors who are involved with creating and filing claims for payment for Providence services will only use true, complete, and accurate information. Providence further expects that those who certify compliance with state and federal law will take reasonable steps to ensure that business practices are compliant.

Workforce members and contractors are expected to report any concerns about billing issues, or any other issue they feel is illegal or otherwise inappropriate. They are required to report the concern to their manager and local or regional compliance office or to the Providence Integrity Hotline.

Providence will notify the appropriate government agency and impacted Health Plan partners of any individuals or entities excluded from federal or state programs, as well as individuals with confirmed compliance and/or fraud, waste, and abuse violations that may have provided services on behalf of the sponsor as applicable.

Referrals

Anti-kickback laws are designed to ensure that financial considerations do not cloud physicians' judgement. Illegal kickback schemes corrupt the healthcare system. They cause billions of dollars in losses each year and erode trust in the health care system.

Federal and state Anti-Kickback Statutes and the federal Stark Law apply to relationships between hospitals and physicians. Providence structures its relationships with physicians to ensure compliance with these laws, with policies and procedures and with any operational guidance that has been issued.

Antitrust

Providence maintains an Anti-Corruption Compliance policy (<u>PSJH-CPP-732</u>). All workforce members and business partners are required to conduct business in accordance with applicable legal and ethical standards and must comply with all applicable laws that prohibit bribery and counter corruption (collectively, the "Anti-Corruption Laws"), including, but not limited to, the U.S. Foreign Corrupt Practices Act of 1977 ("FCPA").

Antitrust laws preserve and protect competition in goods and services. Antitrust violations are serious and may result in criminal charges, substantial fines, and imprisonment. Providence will not engage in conduct that is illegal under antitrust laws. Examples of conduct prohibited by the laws include (1) agreements to fix prices, bid rigging, collusion (including price sharing) with competitors; (2) boycotts, certain exclusive dealing, and price discrimination agreements; and (3) unfair trade practices including bribery, misappropriation of trade secrets, deception, intimidation, and similar unfair practices.

Antitrust is a complex area, workforce members are encouraged to consult the policy and to direct questions or concerns about whether a practice may raise antitrust concerns to the Compliance Program Office or Department of Legal Affairs.

Emergency Medical Treatment and Labor Act

Providence complies with the Emergency Medical Treatment and Labor Act (EMTALA). We screen and provide stabilizing treatment to everyone who comes to a Providence hospital requesting examination or treatment for an emergency condition. We do not delay medical screening exams or stabilizing care to request patient financial information. We transfer emergency patients only when they request a transfer or when we lack the capability or the capacity to provide appropriate treatment, and only after administering the appropriate stabilizing care.

Privacy and Information Security

All covered entities, as defined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), that conduct electronic transactions for which standards have been adopted under the Act are required to comply with the Privacy and Security Rules promulgated pursuant to HIPAA. Generally, the HIPAA Privacy Rule addresses the use and disclosure of individuals' identifiable health information (protected health information or PHI) by covered hospitals and other covered entities, as well as standards for individuals' privacy rights to understand and control how their health information is used. The Security Rule protects the privacy of an individuals' health information while allowing covered entities to adopt new technologies to improve the quality and efficiency of patient care. Given that the health care marketplace is diverse, the Security Rule is designed to be flexible and scalable so a covered entity can implement policies, procedures, and technologies that are appropriate for the entity's particular size, organizational structure, and risks to consumers' e-PHI.

To ease the burden of complying with the requirements, the Privacy and Security Rules gives covered hospitals and other covered entities some flexibility to create their own privacy and security policies and procedures. Each covered entity must make sure that it is compliant with all applicable provisions of the Rules, including provisions pertaining to required disclosures (such as required disclosures to the U.S. Department of Health and Human Services when it is undertaking a Privacy and/or Security Rule investigation or compliance review) in developing its policies and procedures that are tailored to fit its size and needs.

The Providence Privacy Office, a department within the overall Compliance Program, has oversight and governance of the organization's privacy compliance function in relation to the use and disclosure of protected health information (PHI) and personally identifiable information (PII) in compliance with internal policy, state, federal privacy laws. Access review is conducted utilizing a monitoring application to determine if unauthorized and inappropriate access to patient electronic PHI may have occurred. The objective is to ensure proactive detection of inappropriate access violations to protect patient privacy through the application of standardized processes and procedures to promote consistency, integrity, and a privacy compliance culture.

Under the direction of the Chief Privacy Officer, the Privacy Team is responsible for investigating all alleged privacy incidents and for providing guidance to key business functions across Providence to ensure the appropriate use and disclosure of information in compliance with state and federal privacy law and policies and procedures.

The Privacy Program does the following:

- Establishes, monitors, and supports high professional and ethical standards.
- Supports initial and continuing compliance education and training.

- Complies in all material respects with federal, state, and local laws and regulations that are applicable in our operations.
- Maintains a mechanism (through the <u>Integrity Hotline</u> at 888-294-8455) for reporting integrity, compliance, or legal concerns.
- Satisfies the conditions of participation in health care programs funded by the federal and state governments.
- Promotes self-monitoring and provides for, in appropriate circumstances, voluntary disclosure of violations of laws and regulations.
- Reviews, investigates, and acts on allegations of violations and misconduct.
- Ensures a consistent and standardized approach in the application of sanctions working with key operational areas.

Patient and Member Information and Privacy

Providence treats the protected health information (PHI) of patients and members with special care. There are numerous federal and state laws that protect the privacy and security of a patient's information, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH). Providence maintains a privacy policy (PSJH-CPP-850) with several linked technical standards including, but not limited to, the general use and disclosure of PHI, the rights of individuals with respect to PHI, and breach notification. Providence also maintains policies that govern Disclosures to Law Enforcement (PSJH-RESO-1408) and the Identity Theft Standard (PSJH-CYBR-953.07).

Providence maintains an Information Security Management policy (<u>PSJH-CYBR-950</u>) and an Access Management policy (<u>PSJH-CYBR-953</u>) along with several linked technical standards:

- PSJH-CYBR-950.01 Security Risk Management Standard
- PSJH-CYBR-950.02 Security Compliance Standard
- PSJH-CYBR-950.03 Security Assessment and Authorization Standard
- PSJH-CYBR-950.04 Vendor Security Risk Management Standard
- PSJH-CYBR-950.06 Security Exception Processing Standard
- PSJH-CYBR-950.07 PCI Compliance Standard
- PSJH-CYBR-950.08 Acceptable Use Standard
- PSJH-CYBR-953-02 Password Management Standard

Providence ministries collect PHI to provide quality care and service and will protect access to this information whether it is contained in a computer system, medical record, or other documents. Consistent with HIPAA and applicable state laws, we do not access, use, disclose or discuss patient-specific information with others unless it is necessary to serve the patient or complete our job duties, is required by law or the patient/authorized representative has authorized the release. If workforce members use or disclose PHI inappropriately, they may be subject to Providence's corrective actions policy. Workforce members may also face potential fines from the government and/or jail time.

Providence workforce members will not access, use, or disclose PHI in a manner that violates the privacy rights of our patients. Under Providence privacy policies and procedures, no one has a right to access PHI other than the minimum information necessary to perform his or her job.

Workforce members have a duty to report suspected theft, loss or inappropriate uses or disclosures of PHI promptly to their direct supervisor and local or regional privacy office, the system privacy office, or the Providence <u>Integrity Hotline</u> at 888-294-8455.

Workforce members should consult the system, region and facility privacy and security policies and procedures for further information on how to safeguard confidential information and PHI. They may also contact their local or regional compliance and privacy representative, the regional information security office, or the system privacy office with questions.

Patient and Resident Rights

Providence is a place of healing, where caregivers, patients, family members and visitors alike should feel welcome, safe, and respected. We ask and expect all people who come through our doors or seek care with us to behave in a manner that honors everyone's dignity, and helps us to provide high-quality, compassionate care.

At Providence, we believe health is a human right – and every person deserves the chance to live their healthiest life. This means that we care for all by honoring the dignity of each person. We inform our patients and residents of their rights and responsibilities. We expect the people of Providence to uphold and respect these rights.

Each Providence patient or resident is provided with a written or electronic statement of their rights. This statement includes, but is not limited to, the right of a patient or resident to make decisions regarding their medical care, to refuse or accept treatment, to a safe environment, to informed consent and declination of care, to discuss and participate in their health care decisions, to choose their visitors, to continuity of care, to adequate pain control, to understand their financial responsibilities and options for assistance, and to be free of restraints.

Providence maintains a system-wide patient rights and responsibilities policy (<u>PSJH-CLIN-1206</u>). The purpose of this policy is to align Providence around a single, system-wide version of the Patient Rights and Responsibilities ("PRR") document that affirms Providence's commitment to equity. Providence posts the system-wide version of the <u>Patient Rights and Responsibilities</u> document, including how to file a grievance, on our public facing website.

Notice of Privacy Practices

Providence and its family of organizations comply with applicable Federal and State privacy and information security laws. Providence protects all individually identifiable health information that it holds or transmits directly or through an authorized third party, in any form or media, whether electronic, paper, or oral.

In compliance with the Health Insurance Portability and Accountability Act (HIPAA), our patients and residents will receive a copy of our Joint Notice of Privacy Practices. This document provides detailed information about their rights regarding their personal and health information and how that information may be used and disclosed by Providence.

Providence maintains a privacy policy (PSJH-CPP-850) and several privacy standards including but not limited to the notice of privacy practices. Providence posts a system-wide version of the <u>notice of privacy practices</u> on our public facing website in various languages. In addition, each ministry posts a location specific version of this notice.

Notice of Nondiscrimination and Communication Assistance

Providence and its family of organizations comply with applicable Federal civil rights laws and do not discriminate against, exclude, or treat differently any individuals accessing any Providence Program or Activity. In compliance with the Americans with Disabilities Act (ADA), Providence provides qualified interpreters and other auxiliary aids and services free of charge.

Providence maintains a nondiscrimination policy (<u>PSJH-CLIN-1203</u>). Providence posts a system-wide version of the <u>notice of nondiscrimination and communication assistance</u> on our public facing website in various languages. In addition, each ministry posts a location specific version of this notice.

Providence is committed to providing accessible content on our patient facing websites and maintains a web accessibility policy (<u>PSJH-EIS-903</u>).

Additionally, Providence Human Resources maintains a Reasonable Accommodation policy on the <u>Caregiver Service Portal</u>. The purpose of this policy is to support and promote the organization's commitment to good faith efforts in making employment decisions in a non-discriminatory manner, each Providence entity will follow the policy regarding employment practices, including, but not limited to, hiring, promotion, transfer, recruitment or recruiting advertising, layoff or termination, and compensation.

Quality of Care and Patient Safety Program

Providence has been on a multi-year journey in becoming a High Reliability Organization ("HRO") that can predictably achieve safe, high-quality results every time with the goal of zero preventable harm to our patients and workforce members. The HRO work has included specific leader training and training for all caregivers and medical staff members to give them the tools to reduce the types of human errors made in health care and to fix systems and structures to prevent error from happening. HRO serves as the foundation for quality and safety within Providence and the Quality of Care and Patient Safety Program.

The Quality of Care and Patient Safety Program activities focus on continually improving clinical outcomes, clinical processes, patient safety, and organizational processes. Overall guidance and direction for clinical quality and patient safety comes from coordination with Providence System-level committees and directives. Metrics are objective, measurable, evidence-based, structured to produce statistically valid performance measures of care and service, and are described in terms of the key quality characteristic for which their improvement is being measured. Medical record reviews and audits, safety event reports (sometimes referred to as Unusual Occurrence Reports or "UORs"), patient complaint reports, proactive risk assessments, and Root Cause Analysis ("RCA") processes are all examples of tools used throughout the Providence System to support clinical quality improvement. The Quality of Care and Patient Safety Program uses FOCUS-PDSA methodology to plan, design, measure, assess, and improve functions and processes related to our improved clinical outcomes and patient safety. The hospital-based quality committees review the results of the processes described above. Results are also shared with the Medical Executive Committees and the respective governing boards. Processes are in place to ensure associated action plans are appropriate, timely, implemented, and enforced.

Government Inquiries and Investigations

Providence commits to cooperating with government inquires and investigations and maintains standard protocols that involve the Department of Legal Affairs (DLA) and the Chief Compliance Officer as appropriate.

Federal agencies have a variety of investigative tools available to them, including search warrants and subpoenas. Action may also be brought against Providence to exclude it from participating in federally funded healthcare programs if Providence does not grant immediate access to agencies conducting surveys or reviews. Providence is committed to responding appropriately to, and not interfering with, any lawful government inquiry, audit, or investigation. Providence policy is to cooperate with and properly respond to legitimate inquiries and investigations.

Workforce members who receive a search warrant, subpoena, or other demand or request for investigation, or if approached by a federal agency, should obtain the identity of the investigator, and immediately notify their supervisor, regional compliance office, or the DLA. Workforce members should request the government representative to wait until a compliance office representative arrives before conducting any interviews or reviewing documents. Providence may provide legal counsel to caregivers.

Providence's response to any warrant, subpoena, investigation, or inquiry must be complete and accurate. No workforce member shall alter or destroy any document or record whether in paper or computer form, which is on a legal hold.

Providence is committed to responding appropriately to, and not interfering with, any lawful government inquiry, audit, or investigation. If workforce members are contacted by a government investigator with a request for information, they should follow these steps:

- 1. If contacted in person, ask the investigator(s) for identification, note the name, title, and office location.
- 2. If contacted by telephone, ask for and note the name, title, office location and a return phone number for the caller.

Workforce members should contact their supervisor and their region's compliance office or the DLA as soon as possible. Workforce members are not required to follow this procedure before participating in a government investigation concerning the terms and conditions of their employment consistent with state and federal laws.

Emergency Preparedness and Incident Response

Emergency Management: Our role is to bring together our emergency managers from across the system to engage in collaboration, standardization, and information sharing in an overall organizational planning and response approach.

Incident Response: We monitor on a 24/7 basis, alerts to natural or man-made disasters where our ministries and workforce members serve. We evaluate each alert, verify, collaborate with local emergency managers, and report as needed to system leaders based on the situation.

Business Continuity Program: When business is disrupted for a sustained period, continuity of business needs to continue, and we provide the identified critical areas in the ministries with the tools and training to document those processes and regularly exercise them to comply with regulatory requirements.

Physician Compliance Services

The Physician Compliance Services Program (the Program) is embedded within the overall Compliance Program under the leadership of the Chief Compliance Officer. The Program integrates the seven elements of effective compliance programs and the Department of Justice (DOJ) advice to prosecutors to maintain a proactive approach to compliance.

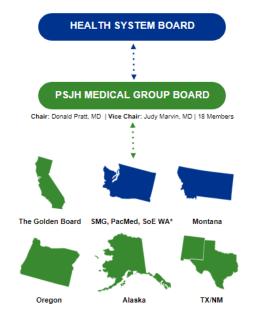
The <u>OIG Compliance Program Guidance for Individual and Small Group Physician Practices (hhs.gov)</u> states that a well-designed compliance program can:

- Speed and optimize proper payment of claims;
- Minimize billing mistakes;
- Reduce the chances that an audit will be conducted by the Health Care Financing Administration (HCFA) or the Office of Inspector General (OIG); and
- Avoid conflicts with the self-referral and anti-kickback statutes.



The Program focuses on Providence's relationships with its physician workforce. One part of the Programs mission regards the ministry medical staffs. The Program partners with Chief Medical Officers, Medical Directors, and Medical Staff Leadership to optimize compliant operations related to credentialing and other medical staff functions. Another part of the Programs mission relates to Providence Physician Enterprise, and the compliance issues relevant to directly employed, medical foundation-contracted and affiliate physicians.

♯ Providence We're Partnering with Physicians



Value-Based Care model requires:

- Strong physician leadership
- Unified provider voice
- · Formal governance structure

Value of creating a large medical group:

- Culture
- Accountability
- Performance

GREEN indicates regional medical group governing structures in place. BLUE indicates regional medical group governing structures in development.

*PacMed and SMG structures is in place.

The Program delivers compliance education and consults on compliance matters with leaders on the above Boards.

The Program also sends an important message to a physician practice's employees that while the

practice recognizes that mistakes will occur, employees have an affirmative, ethical duty to come forward and report erroneous or fraudulent conduct, so that it may be corrected.

By partnering with Physician Enterprise, medical foundations, and medical group leadership, the Program grows compliance by building thoughtful guardrails.

Compliance Committee of the California Medical Foundations Board

This chartered Committee includes and is also known as the Compliance Committee of the California Medical Foundations Board ("The Board") of Providence Facey Medical Foundation, Providence Medical Institute, Providence Saint John's Medical Foundation, and Providence Medical Foundation.

The role of the Board is to oversee the various areas relating to healthcare compliance and related regulatory issues of the four above-listed California Medical Foundations (the "Foundations"). The Compliance Committee (the "Committee") will serve concurrently as the Compliance Committee for the Foundations and will serve an identical role for each such Foundation.

The Physician Compliance Services Leader (or his/her designee on the Committee) shall serve as Chair of the Committee. Additionally, the Physician Compliance Services Leader shall have unencumbered access to and dotted line reporting to the Board and Chair thereof, with day-to-day input and interaction with members of the Corporation's management. See the Committee Charter for details as to scope and authority of the Committee.

Physician Contracting

Physician Compliance Services coordinates the Physician and Advanced Practice Clinician Payment Oversight Council (PAPOC), a senior interdisciplinary team that is developing a process which will monitor and oversee an organization wide physician contracting process. The Council relies on communication with regions and lines of business through the workgroups formed to support the council. The scope of this Council is to:

- 1. Develop and deliver goals and strategies to enhance and standardize where possible Physician and Advanced Practice Clinician (APC) compensation and contracting processes across the system
 - a. Review associated policies to ensure accuracy and reduce local and regional variation
 - b. Ease the way of stakeholders involved in Physician and APC contracting processes
 - c. Mitigate risks, increase efficiency, and simplify where possible and needed
- 2. Implement a standardized set of minimum specifications with an end goal of system-wide Physician and APC contracting processes
- 3. Develop a standardized process to review exceptions
- 4. Define and refine the roles that participate in Physician and APC contracting processes
- 5. Align and integrate cross-organizational Physician and APC performance metrics

Pharmacy Compliance Services

Compliance is a crucial component of any successful pharmacy, regardless of size, location, or specialty. The Pharmacy Compliance Program (the "Program") is embedded within the overall Compliance Program under the leadership of the Chief Compliance Officer. The Program strives to promote best practices and ethical behavior in all areas of pharmacy across Providence and deter activity contrary to these standards through education, audit, and monitoring activities. The Program not only includes activities within licensed pharmacies, but also various activities occurring outside the pharmacy construct (e.g., prescribing and administering drugs across our physician enterprise). The Program serves as a resource to all caregivers, investigators, and compliance supporting staff who

participate in pharmacy or pharmaceutical compliance activities. Because regulations vary across the country, our system requires a customized plan that protects patients and helps providers avoid liability. Failure to meet compliance standards can mean being removed from health plans and networks, facing fines and other legal consequences, or even endangering patients.

The Program partners closely with system and regional clinical leadership as well as compliance leadership, legal, and various other stakeholders to provide consultation in various pharmacy compliance areas. The Program is a trusted advisor to pharmacy leadership and operations in the following areas: Compliance Monitoring; Education; Audit Support; Investigation Support; Committee Facilitation/Participation. Providence must comply with a growing number of pharmacy-related regulations from various state and federal agencies. The frequency of audits and the monetary penalties for non-compliance are increasing. The Program helps relieve the stress caused by setting up policies, procedures, and training programs to comply with current regulations, as well as in keeping track of any new legally required changes.

Laboratory Compliance Services

The Laboratory Compliance program (the "Program") is embedded within the overall Compliance Program under the leadership of the Chief Compliance Officer. The Program integrates the seven elements of effective compliance programs and the Department of Justice (DOJ) advice to prosecutors to maintain a proactive approach to laboratory compliance. By embedding in the operational fabric of laboratory service provision at Providence, we assure that risk assessment and compliance controls are embedded into operational deployments by facilitating a System Laboratory Compliance Committee (SLCC) that supports local compliance monitoring and corrective action. The SLCC also promotes best practices and maintains compliance standards for known risk areas.

The Program maintains expertise in regulation and enforcement to advise all areas of laboratory service provision. Associated compliance specialties like privacy, research, and investigations, are heavily matrixed in Compliance. The Program leverages this expertise to assure those areas of focus are attuned to laboratory services. This proactive approach allows the Program to minimize adverse events and reactive compliance; thus, adding value to operational investment.

The Program maintains ninety-eight standards in known risk areas for laboratory services. These standards guide practice for clarifying laboratory orders, documenting patient interactions, knowing patient's rights, delivering advanced beneficiary notice, registration requirements, billing requirements, and establishing medical necessity. In addition, the Program monitors chargemaster maintenance, charge trigger and billing, claims denials, provider test utilization, and assists with investigation of fraud, waste, and abuse.

The Program educates all lab caregivers annually on compliance issues related to laboratory services. The Program communicates annually with providers on Medicare requirements and areas of known risk. The Program maintains records of compliance activities and deliberations.

Evidence of discernment and compliance are maintained in accordance with the Providence Records Retention and Disposal policy. Expected outcomes and practices are periodically revalidated using selfmonitoring checklists. Risk assessments are also repeated on a periodic basis to revalidate known risks and surveil for emerging risks. Known risks are prioritized by likelihood and severity. When possible, controls or monitors are put in place to mitigate known risks.

Global Compliance

Providence has established its first global footprint at Hyderabad, India through the Providence Global Center (PGC). PGC focuses efforts on healthcare technology and plays a pivotal role in driving digital

transformation for improved patient outcomes and experience. PGC adheres to internal compliances as prescribed by the compliance program considering the local statutory, legal, and country-specific requirements. Policies, procedures, and guidelines from <u>PolicyStat</u>® are made applicable in alignment with PGC's nature of operations and relevance. In country Risk and Compliance staff is assigned to implement the risk and compliance initiatives at PGC. Mandatory trainings on compliance are administered to caregivers upon joining PGC and annually through the training curriculum adopting a risk-based approach. Additionally, a dedicated <u>Integrity Hotline</u> number is available to all PGC caregivers to report concerns.

All third-party vendors and partners at PGC are screened prior to contracting for sanctions, exclusions, criminal conduct, adverse media, and other red flags. A third-party background and exclusion screening company with expertise in thorough background screening processes is used for an additional level of review. Any red flags identified are reviewed and appropriate action is taken, to include declining to engage with the vendor. Once vendors are contracted and onboarded, continuous monitoring activities are in place to assure ongoing compliance with policies and procedures.

Global Third-Party Due Diligence and Management

For international operating locations, third-party vendors and partners are screened prior to contracting for sanctions, exclusions, criminal conduct, adverse media, and other red flags. A third-party background and exclusion screening company with expertise in thorough background check processes is used for an additional level of review. Any red flags identified are reviewed and appropriate action is taken, to include declining to engage with the vendor. Once vendors are contracted and onboarded, continuous monitoring activities are in place to assure ongoing compliance with policies and procedures.

Key Policies and Foundational Materials

The Program has established Providence-wide policies, charters, and guidance to define and support the on-going effectiveness of the Compliance Program for Providence.

The Providence-wide policies are posted on the <u>PolicyStat®</u> platform available to all members of the workforce organization-wide. For the most up-to-date version of the policy, please refer to the version posted on <u>PolicyStat®</u>.

Policies and supporting materials directly applicable to this book are listed in the Appendices for internal members of the workforce.

Additionally, Compliance, the Department of Legal Affairs, and other appropriate departments provide supplementary compliance guidance on legal and regulatory compliance through publication of periodic regulatory memoranda and guidelines.

[Remainder of Page Left Intentionally Blank]

Book 2: Designating a compliance officer and compliance committee

The OIG's compliance guidance for this element states: The designation of a chief compliance officer and other appropriate bodies, e.g., a corporate compliance committee, charged with the responsibility of operating and monitoring the compliance program, and who report directly to the CEO and the governing body.

The compliance department is the backbone of Providence's compliance program. The compliance department is led by a well-qualified compliance officer, who is a member of senior management, and is supported by a compliance committee structure. The purpose of the compliance department is to implement Providence's compliance program and to ensure that the organization complies with all applicable Federal health care program requirements. To ensure that the compliance department is meeting this objective, Compliance conducts an annual review of the compliance program functions. Some factors that may be considers in its evaluation include the following:

- Does the compliance department have a clear, well-crafted mission?
- Is the compliance department properly organized?
- Does the compliance department have sufficient resources (staff and budget), training, authority, and autonomy to carry out its mission?
- Is the relationship between the compliance function and the general counsel function appropriate to achieve the purpose of each?
- Is there an active compliance committee, comprised of trained representatives of each of the relevant functional departments, as well as senior management?
- Are *ad hoc* groups or task forces assigned to carry out any special missions, such as investigating or evaluating a proposed enhancement to the compliance program?
- Does the compliance officer have direct access to the governing body, the president or CEO, all senior management, and legal counsel?
- Does the compliance officer have independent authority to retain outside legal counsel?
- Does the compliance officer have a good working relationship with other key operational areas, such as internal audit, coding, billing, and clinical departments?
- Does the compliance officer make regular reports to the board of directors and other senior leaders concerning different aspects of the organization's compliance program?

Providence has created and fosters a culture of ethics, integrity, and compliance with the laws, regulations, and industry best practices at all levels of the company. Starting with the organization's top leaders, the Providence Board of Trustees (the "Board") through its Audit and Compliance Committee (ACC) has oversight of reviewing and approving related workplans and monitoring their status for implementation by the Providence Compliance Program (the "Program").

Providence is committed to acting with integrity in all we do. We require compliance with laws and regulations, the Code of Conduct and Providence policies and standards. The Program applies to Providence St. Joseph Health and its Affiliates (collectively known as "PSJH") and their workforce members (caregivers, volunteers, trainees, interns, apprentices, students), independent contractors, vendors and all other individuals working at the ministry, whether they are paid by or under the direct control of the facility); employees of affiliated organizations (collectively, "workforce members"); members of the PSJH System Board; Community Boards; and Foundation Boards.

The ACC of the Board provides oversight and direction for the Compliance Program. For questions contact the Providence Chief Compliance Officer.

Providence maintains a Compliance Program policy, <u>PSJH-CPP-700</u>. This policy supports the Compliance Program Description and provides the plan and framework for the organization to maintain an effective Compliance Program consistent with the organization's commitment to high ethical standards of corporate conduct and compliance with regulatory and statutory requirements.

Compliance offices across Providence are responsible for the day-to-day direction and implementation of the Program. This includes developing resources (policies, procedures, education programs and communication tools) and providing support (managing the Providence Integrity Hotline and other reporting mechanisms, conducting program assessments, and providing advice) to ministry compliance representatives and others.

Providence Human Resources staff members are also highly knowledgeable about many of the employment and workplace compliance-risk areas described in this document. Workforce members are encouraged to report any concerns about their work situation to Human Resources. Our compliance professionals work closely with Human Resources to investigate and resolve matters relating to employment and workplace situations.

Providence Compliance Program Core Elements

The Program is designed with the elements recognized by the Office of Inspector General (OIG), the Department of Justice (DOJ) compliance program guidance and best practices of an effective compliance program. These key elements of the Program include:

- 1. Implementing written policies, procedures, and standards of conduct
- 2. Designating a compliance officer and compliance committee
- 3. Conducting effective training and education
- 4. Developing effective lines of communication
- 5. Conducting internal monitoring and auditing
- 6. Enforcing standards through well-publicized disciplinary guidelines
- 7. Responding promptly to detected offenses and undertaking corrective action
- 8. Ongoing risk assessment

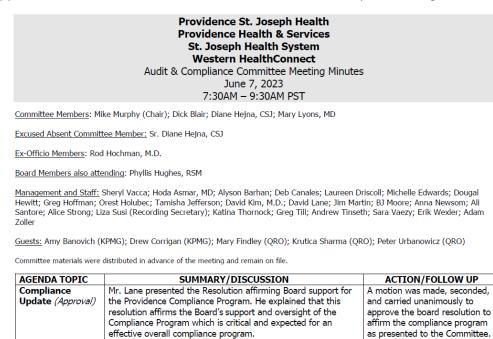
Providence Board Resolution to Affirm the Compliance Program

The Chief Compliance Officer ensures that the Providence Board of Directors is aware of and affirms the Compliance Program. This is done through a Board resolution document that includes but is not limited to:

- Providence and its affiliated entities have established a systemwide program of corporate compliance and established the positions of Chief Compliance Officer; and
- management, including, President and CEO Rod Hochman strongly endorses and recommends that Providence has a robust ethics and compliance program; and
- the structure for an effective Compliance Program for Providence has been established and implemented; and
- a strong compliance program supports and is integral to the mission, values, and vision of Providence; and
- voluntary adoption of such a program is considered a best business practice that will serve to enhance the public trust and meet the expectations of the Board and external

stakeholders by demonstrating the Board's commitment to good stewardship of federal, state, and private resources; and

- Providence, in partnership with the ministries, has implemented an effective compliance program that includes, but is not limited to, the requisite elements of an effective Compliance Program; and
- the Chief Compliance Officer and caregivers in Compliance are primarily responsible to assure that ministry responsibilities are executed related to compliance matters and to assess and monitor that ministry compliance systems and controls are effective; and
- that the Board of Directors/Trustees for Providence and its affiliated entities does hereby approve and re-affirm the structure of the Providence Compliance Program.



The Chief Compliance Officer

Leadership at Providence recognizes that integrity and compliance are driven by involvement and responsibility at the top. Providence has designated a Chief Compliance Officer (CCO), who is responsible for effectively overseeing the implementation of the Program. The Chief Compliance Officer is a highranking employee who serves as a member of Providence's senior management. The Chief Compliance Officer reports directly to the Chief Operating Officer (COO), who is not subordinate to the General Counsel, Chief Financial Officer, or Chief Operating Officer. Additionally, the Chief Compliance Officer does not have any responsibilities requiring them to act as legal counsel or a supervising legal counsel for Providence.

The Chief Compliance Officer assures that the System Board, the ACC, and senior executives receive periodic reports concerning implementation of the Program, at least quarterly. The Chief Compliance Officer has direct access to the ACC Chair and senior management, enabling them to provide timely information and updates, as necessary. Providence has ensured the independence of the Program by concentrating the compliance resources within the Compliance division and articulating to its workforce

as presented to the Committee.

the importance of this independence. The Chief Compliance Officer continues to reinforce the independence of the Program and that it operates "outside of management functions".

The Chief Compliance Officer collaborates with the Chief Operating Officer, General Counsel, and other executive leadership to provide assurance that our organization materially meets the elements of an effective compliance program as set forth by regulatory requirements and legal guidance. With the elevated status of the Chief Compliance Officer, an independent budget, and support from senior leadership, the Chief Compliance Officer has sufficient autonomy and authority to remedy issues identified through the Program.

Compliance Department

Providence has dedicated compliance resources through the Chief Compliance Officer and Compliance workforce members. These resources are used to ensure a culture of compliance has been integrated into every layer of the organization. The Chief Compliance Officer has designated Regional Compliance Directors (RCDs) and local compliance liaisons who support workforce members on the front line. The compliance liaisons work with facilities and regional management to promote the Program, identify issues, and mitigate risks by providing relevant compliance guidance regarding day-to-day responsibilities.

Besides providing core compliance services to the regions of Providence where the fifty-two hospitals lie, Providence has aligned compliance professionals across key risk areas such as research; coding, documentation & billing; privacy; pharmacy; laboratory; and physician arrangements (regardless of geography or business unit) which enables consistency in guidance and prompt identification of risk trends. Furthermore, Providence has invested in technologies to scale risk sensing capabilities across the organization that result in greater cross-functional collaboration and efficiencies.

Given the complexity of Providence the Program partners, collaborates, and receives regular reports directly from compliance professionals in other, affiliated, and networked parts of the organization such as:

- Providence Global Center
- Home and Community Care
- Providence Health Plan
- Ambulatory Care Network
- Providence Ventures
- Tegria
- California Medical Foundations
- University of Providence
- Providence High School

Providence Council Structure

Providence has instituted a council structure to navigate the size, scale, and scope of the organization. The council structure empowers the organization's work to be collaborative and streamlined to achieve its strategic priorities. The council structure includes:

- Executive Council
 - Clinical Operations Council
 - Strategy & Growth Council
 - Workforce Council

The council structure is central to Providence's ability to deliver on its vision of health for a better world. This structure empowers the three councils to work collaboratively to achieve a streamlined set of strategic priorities across Providence and its family of organizations. Chartered by the Executive Council, these councils are inclusive of the divisions, regions, lines of business and other key functional areas. The councils consist of many key leaders who impact the culture of compliance at the top of the organization, creating leverage for the Chief Compliance Officer to respond to compliance concerns efficiently and effectively. The Compliance Program and its overarching risk portfolio are tied into the council structure.

While the Compliance Program interacts with all three Councils, the Chief Compliance Officer is an active member on the Strategy & Growth Council. Additionally, the Chief Compliance Officer is an active member of the Executive Council.

The core purpose of Executive Council (EC) is to provide a dedicated forum for executive-level strategic and operational discussion, updates, and decision-making for selected topics that advance the Mission and Vision of Providence. The ongoing functions of EC are:

- Maintain a forum via informational packets for knowledge transfer and sharing of information that benefits EC members but that does not require discussion or decision-making
- Maintain a dedicated forum for discussing key topics and seeking alignment between stakeholders. This includes but is not limited to System-wide initiatives, key strategic or operational topics, significant policy changes, and other topics as identified by EC members and/or CEO Council
- Maintain a dedicated forum for ensuring review, discussion, and accountability across key metrics including Metrics in Common, Council Metrics, and other system metrics (e.g. ESG, digital, behavioral health, etc.) and activities including Recovery & Renewal
- Responsible for final management approval (prior to Board approval, as needed) for the Providence Strategic Plan, budget, and performance metrics. Also responsible for ongoing review of metric performance throughout the year

The Executive Council includes the top executive management group for Providence, convened to set Providence's strategic direction and advance the Mission. The EC collaborates, removes barriers, monitors progress, and cascades in a unified voice for these Committees. The EC also serves as the System Compliance Committee.

The EC provides input to the three Councils and the System Compliance Committee through:

Consultation - Provides input on upcoming strategic focus areas **Change Leadership** - Provides support for uniting and implementing across Providence and its family of organizations through communication, engagement, and enablement **Removal of barriers** - Helps to remove barriers and provides support from a division, line of business and function perspective.

Performance monitoring - Monitors Council focus areas and success measures

The role of the System Compliance Committee is to review compliance and privacy risks, plans, responses, activities, and mitigation strategies to support, improve, and enhance the integrity and compliance efforts of Providence. This Committee reviews the progress and updates from the various Division Compliance Committees, and looks at overarching systemwide issues, needed policies and procedures and compliance operational decisions including the annual compliance work plan. The Committee's purpose is to aid and support the compliance officer in implementing, operating, and monitoring the Compliance Program.

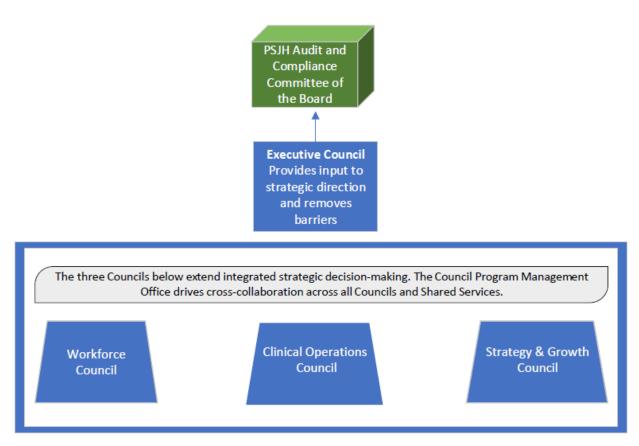
The Chief Compliance Officer participates in subcommittees that work under and with the various Councils at their direction including but not limited to:

• Physician and Advanced Practice Clinician (APC) Payment Oversight Council

- Quality Sub-Committee of the Clinical and Medical Group Council
- Revenue Cycle /R1 Executive Steering Committee
- Government Affairs and Reimbursement Committee
- Interoperability Committee
- Investment Review Committee
- Diversity, Equity, and Inclusion (DEI) Workforce Committees
- Providence Data Protection Committee
- Tegria Governance Committee

In addition to the System Compliance Committee, the Compliance Program has division committees that focus on compliance oversight independently of management and operations. The work of the Division Compliance Committee (DCC) is carried out within respective regional and/or lines of business to support management in ensuring the activities of Providence ministries and associated caregivers are in accordance with Providence policies and procedures and applicable federal, state, and local laws/regulations. They are convened to identify compliance risks, share knowledge, and help coordinate compliance risk mitigation efforts. The committees serve as an advocate for compliance by supporting activities and initiatives that promote a culture of compliance in the region. Membership of the DCC includes senior leaders and representatives from key functions across Providence.

Color Key: Blue boxes indicate active membership of the Chief Operating Officer. The green box indicates the reporting relationship of the Councils to the Providence Board.



In addition to the Council structure, the Program has specific committees across the organization that focus on compliance oversight independently of management and operations.

Functional or Operational Compliance Committees: Other regional, service area, and/or line of business compliance committees are established as needed or as the governance or structure of Providence evolves. Some of these committees are ongoing; others are time-based depending on need. The goal of these committees is to respond to risks and compliance needs of the organization. Some of the compliance functional and operational committees include:

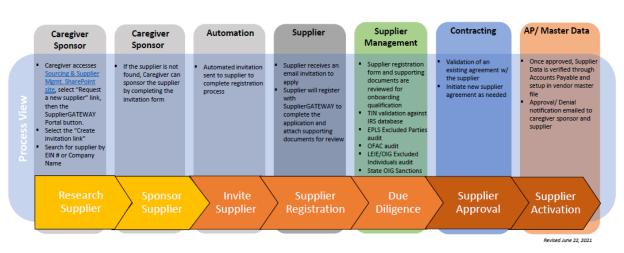
- System Lab Compliance Committee
- Lab Quality and Compliance Council
- Lab Clinical Performance Group
- Lab CDM Billing workgroup
- Epic (electronic medical record (EMR)) Governance and Compliance Committee
- Epic Security Review Board
- Policy Advisory Committee (organization-wide policy oversight)
- Interoperability Committee (digital innovation)
- Cyber StandUP
- Revenue Cycle Growth & Expansion (vet New Lines of Service Compliantly)
- Pharmacy Compliance and Accountability Committee (PCAW)
- Controlled Substance Diversion Prevention Committee (CSDPC)
- 340B System Workgroup (not technically a compliance committee but has a compliance function)
- Compliance Committee of the California Medical Foundations Board
- Mandated Provider Education Sub-Committee (of the Compliance Committee)
- Compliance Committee of the Providence Medical Group (systemwide) Board
- Compliance Committee of the Oregon Medical Group Board
- Provider APC and Payment Oversight Committee
- Coding Compliance Oversight Committee
- Americans with Disabilities Act (ADA)/Civil Rights and Diversity, Equity, and Inclusion Compliance Committee

Third-Party Management

Providence endeavors to conduct business with third parties in a way that maximizes the ability of its workforce to carry out patient care, research, and educational missions in compliance with legal and ethical standards aimed at preventing conduct that may inappropriately influence business decisions. Providence manages third-party enterprise risk by expecting partners to 1) provide standard business information including the submission of tax identification information; 2) comply with Providence organization-wide and local facility-specific policies; and 3) complete required health, exclusion, and background screenings.

Providence recognizes the importance of establishing credible business relationships with qualified third parties to ensure quality patient care and business continuity. To ensure there is appropriate business rationale for the use of third parties, interested partners must complete a stringent registration and assessment process prior to providing any product(s) or performing business service(s) to Providence. An element of Providence's qualification process includes registration through the Resource, Engineering and Hospitality Group (REH), which is a shared central service division that manages the evaluation and supplier-onboarding process for Providence.

The REH group ensures that the products and services Providence purchases meet the clinical needs of the patients and caregivers we serve. Providence partners with diverse suppliers that range from multinational corporations to small, locally based businesses. For additional information regarding our suppliers please refer to the Supplier Onboarding policy (<u>PSJH-REH-1006</u>) and/or the <u>Supplier Information</u> portal on our public facing website.



PROVIDENCE SUPPLIER ONBOARDING PROCESS FLOW

The evaluation & review process will take at **minimum 30 days** to complete and may take longer depending on the thoroughness & accuracy of information submitted, contract value, type of product or service and/or transaction volume.

Providence prohibits contracting with, or using the services or supplies of, individuals or entities listed by a federal agency as: debarred, excluded, or otherwise ineligible for participation in federally or state funded health care programs. All contracts with suppliers or vendors include language affirming that the supplier or vendor is not excluded, or expecting to be excluded, from participation in Medicare or State healthcare programs. Contracts further require that suppliers and vendors have an affirmative obligation to notify Providence if they receive notice that the HHS-OIG, U.S. General Services Administration (GSA) or Office of Foreign Assets Control (OFAC), (SDN) or state Medicaid is excluding, intends to exclude, or proposes to exclude them from participation in Medicare or State healthcare programs.

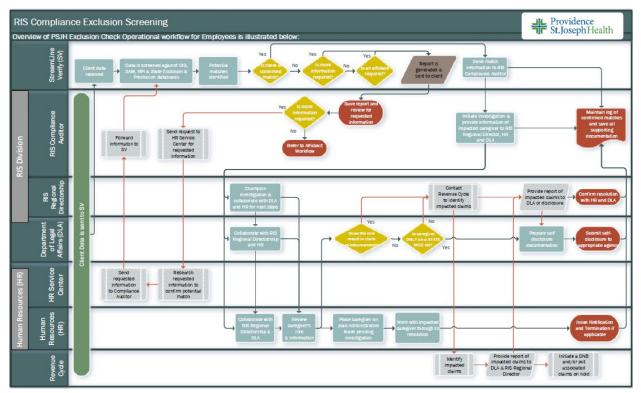
Non-contracted suppliers or vendors are screened against the OIG and GSA/System for Award Management (SAM) and all available state Medicaid databases. In addition, all existing vendors are screened against the OIG and GSA/SAM, OFAC, SDN and all state Medicaid lists monthly. If a vendor is found to be on any of the OIG or GSA/SAM, OFAC, SDN and or all State Medicaid lists, Compliance will expeditiously initiate an investigation including appropriate individuals from REH, Accounts Payable and the Department of Legal Affairs with a recommendation to refrain from using the excluded individual or entity until the matter can be resolved.

The Program has worked with human resources, legal affairs, leadership, Supply Chain & Purchasing, and other offices to establish a standard process for reviewing any potential matches on any exclusion list.

Additionally, Providence maintains the following exclusion screening policies for caregivers/employees, medical staff, and vendors.

- Background Check and Excluded Individuals policy on the <u>Caregiver Service Portal</u>
- <u>PSJH-GOV-217</u> Background Check for System Board of Directors, Community Governance, and Foundation Boards
- <u>PSJH-MED-308</u> Excluded Individual Checks Medical Staff
- <u>PSJH-REH-1005</u> Excluded Individual and Entities Checks Vendors

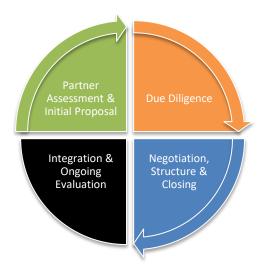
There are separate exclusion screening process flows for employees, global partners, vendors, and members of the medical staff. Below is an example of the exclusion screening process flow for employees. For additional information please refer to the exclusion screening process documents for employees, global partner vendors, medical staff, and vendors.



Mergers & Acquisitions

Providence has a pre-acquisition due diligence team that reviews all proposed mergers and acquisitions (M&A). The Providence M&A Due Diligence Team (DDT) along with the Investment Review Team (IRT) conduct a risk review for acquired/merged entities. The DDT includes representatives from Compliance, including subject-matter experts in compliance, privacy, and physical security. The DDT utilizes a standardized playbook process (see the M&A Playbook Overview document for additional details) for due diligence and integration efforts. The IRT receives proformas and detailed proposals for discernment around new initiatives. Compliance and Risk leaders participate in the review and will conduct various actions as needed to ensure compliance. When the review is completed, recommendations are reported to the Providence Operations Council.

The Project Lifecycle consists of four standard phases with defined phase gates or transition points.



Identified risks are either mitigated prior to closing the transaction, or the proposed deal does not move forward. When Providence is the majority-owner in a joint venture, or wholly owns the new entity, the new entity is provided Providence's policies and held to its standards.

Key Policies and Foundational Materials

The Program has established Providence-wide policies, charters, and guidance to define and support the on-going effectiveness of the Compliance Program for Providence.

The Providence-wide policies are posted on the <u>PolicyStat®</u> platform available to all members of the workforce organization-wide. For the most up-to-date version of the policy, please refer to the version posted on <u>PolicyStat®</u>.

Policies and supporting materials directly applicable to this book are listed in the Appendices for internal members of the workforce.

Additionally, Compliance, the Department of Legal Affairs, and other appropriate departments provide supplementary compliance guidance on legal and regulatory compliance through publication of periodic regulatory memoranda and guidelines.

[Remainder of Page Left Intentionally Blank]

Book 3: Conducting effective training and education

The OIG's compliance guidance for states: Providing appropriate education and training is a vital component of an effective compliance program. The compliance officer, with the support and aid of the Compliance Committee, should develop and coordinate a multifaceted education and training program specific to the needs of and risks presented by the entity. The program should include education and training on the entity's compliance program, Federal and State standards applicable to the entity, and board governance and oversight of a health care entity.

All board members, officers, employees, contractors, and medical staff (if applicable) of the entity should receive training at least annually on the entity's compliance program and potential compliance risks.

Failure to train and educate members of the workforce adequately risks liability for the violation of health care fraud and abuse laws. The purpose of conducting a training and education program is to ensure that each employee, contractor, or any other individual that functions on behalf of the covered entity is fully capable of executing his/her/their role in compliance with rules, regulations, and other standards. In reviewing the compliance training and education program, Compliance will consider the following factors:

- Does the organization provide qualified trainers to conduct annual compliance training for its staff, including both general and specific training pertinent to the staff's responsibilities?
- Has the organization evaluated the content of its training and education program on an annual basis and determined that the subject content is appropriate and sufficient to cover the range of issues confronting its workforce?
- Has the organization kept up to date with any changes in Federal health care program requirements and adapted its education and training program accordingly?
- Has the organization formulated the content of its education and training program to consider results from its audits and investigations; results from previous training and education programs; trends in hotline reports; and OIG, CMS, or other agency guidance or advisories?
- Has the organization evaluated the appropriateness of its training format by reviewing the length of the training sessions; whether training is delivered via live instructors or via computer-based training programs; the frequency of training sessions; and the need for general and specific training sessions?
- Does the organization seek feedback after each session to identify shortcomings in the training program, and does it administer post-training testing to ensure attendees understand and retain the subject matter delivered?
- Has the organization's governing body been provided with appropriate training on fraud and abuse laws?
- Has the organization documented who has completed the required training?
- Has the organization assessed whether to impose sanctions for failing to attend training or to offer appropriate incentives for attending training?

Providence recognizes that ethics and compliance education is required to provide its workforce members with the knowledge and skills needed to carry out their responsibilities in compliance with regulatory and policy requirements and in an ethical manner.

Providence provides compliance education programs to communicate and educate on policies, procedures, and standards in a practical and understandable manner. These educations exist in a variety of content areas and occur at the system, regional and facility levels.

Initial and continuing education of workforce members is a significant element of an effective compliance program. Compliance educational requirements and delivery is tailored according to a workforce member's responsibilities. Both one-time and continued education programs are provided.

Compliance with all applicable laws and regulations is one of Providence's top priorities. To ensure our workforce members know about, and understand, the myriad of federal (including Medicare required fraud, waste, and abuse topics), state, and local healthcare laws and regulations, Providence has a robust education and training program. Compliance with these laws and regulations is achieved through mandatory upon hire, annual, and supplemental "as needed" education (that may encompass part of corrective action plans for policy violations) for all workforce members. The content is reviewed on an annual basis to encompass risks, trends, and new and changing regulations. All mandatory education emphasizes our non-retaliation policy. Workforce members who fail to comply with mandatory education requirements including applicable laws, rules, guidelines, as well as Providence policies, are escalated to managers and senior leaders for corrective action, up to and including termination.

The annual training also provides a general overview of the integrity and compliance program, the hotline reporting process, the <u>Providence Code of Conduct</u> (which may be supplemented by another specific code related to a business area and confidentiality agreement), and a discussion of our organization's commitment to integrity and compliance. For international operating locations, additional education is provided to include coverage of anti-corruption and bribery policies and practices.

New workforce members receive compliance education consisting of a welcome message from the Chief Compliance Officer, an overview of the applicable Code of Conduct and policy, a summary of the key elements of the Compliance Program, including the reporting process, significant compliance policies and procedures and a discussion of Providence's commitment to compliance in its business practices.

Role-based compliance education is provided through an e-learning system and may be offered to workforce members working in quality, long-term care, hospice, nursing, medical records, coding, admitting and registration, radiology, internal medicine, Providence Health Plans, and other key areas of Providence from time-to-time based on identified need.

The Providence Code of Conduct is distributed in new hire orientation and in the annual compliance, privacy, and information security education. It is typically provided electronically to caregivers and agents prior to hire or engagement but in no event later than 90 days of hire or engagement. Acknowledgement of the Code of Conduct and signature by caregivers and agents (collectively workforce members) is required. Thereafter, any changes to the Providence Code of Conduct will be communicated, and a link will be provided at the time of the change and included in new hire orientation and annual education updates.

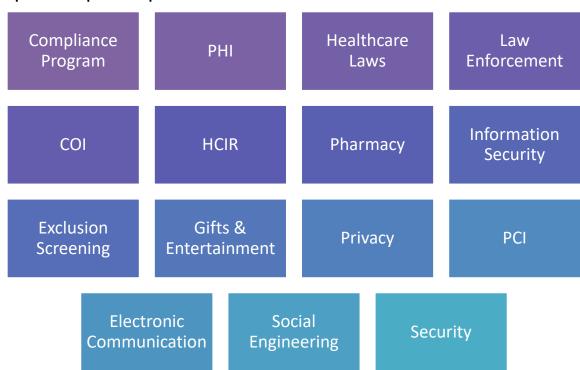
New Workforce Member Orientation On-boarding Requirements: Each new workforce member must complete assigned education as part of the orientation process no later than 90 days of hire. This education includes information about the Program and methods for contacting Compliance and raising any concerns. The Compliance Education Development Team reviews and revises compliance, privacy, and security course content annually.

 The delivery method for new workforce member education provides an opportunity to learn the information and to test for comprehension by requiring workforce members to answer questions before moving on and completing the required content. New hire education is delivered either via one of two learning management systems, <u>HealthStream</u>[®] or <u>Rise</u>[®].

Annual Education Requirements: Current workforce members (those hired prior to the current year) must complete assigned education by the due date established by the Compliance Education

Program. Automated reminders are sent to workforce members as the course deadline approaches and after the due date with a copy to the one-up manager. The Compliance Education Development Team reviews and revises compliance, privacy, and security course content annually. Completion percentages are sent to the regional and ministry leaders for assuring completion requirements are met.

• The delivery method for current workforce member education provides the opportunity for the workforce member to test their knowledge by answering questions first before reviewing the supporting content. This annual course is delivered via <u>Qstream</u>[®], an adult learning competency-based tool that was designed to combat the "forgetting curve", improve long-term knowledge retention, and boost learner proficiency. Example content for the annual education is included below.



Examples of Compliance Topics Included in Education

In addition to those listed above, Compliance covers training specific to Emergency Medical Treatment and Labor Act (EMTALA), patient and resident rights, and patient and member information and privacy in both new hire and annual compliance education materials.

Patient and Member Information and Privacy

All hospitals that conduct electronic transactions for which standards have been adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) are required to comply with the Privacy and Security Rules promulgated pursuant to HIPAA. Generally, the HIPAA Privacy Rule addresses the use and disclosure of individuals' identifiable health information (protected health information or PHI) by covered hospitals and other covered entities, as well as standards for individuals' privacy rights to understand and control how their health information is used. While the Security Rule specifies a series of administrative, technical, and physical security safeguards for hospitals that are covered entities and other covered entities to use to assure, among other provisions, the confidentiality of electronic PHI.

Providence treats the protected health information (PHI) of patients and members with particular care. There are numerous federal and state laws that protect the privacy and security of a patient's information, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH).

We collect PHI to provide quality care and service and will protect access to this information whether it is contained in a computer system, medical record, or other documents. Consistent with HIPAA and applicable state laws, we do not access, use, disclose or discuss patient-specific information with others unless it is necessary to serve the patient or complete our job duties, is required by law or the patient/authorized representative has authorized the release. If workforce members use or disclose PHI inappropriately, they may be subject to Providence's corrective actions policy. Workforce members who misuse PHI may also face potential fines from the government and/or jail time.

With the automated tool, compliance, privacy, and security education includes questions and information to track understanding for both new hires and annually for existing workforce members. Compliance tracks the top six missed questions annually and develops compliance webinars to promote awareness and understanding around the content. The previous year's feedback from cross-operational areas is provided to the compliance education development team for consideration when developing upcoming mandatory education course content. The education development team reviews and revises compliance, privacy, and security course content annually. Specific "one-off" trainings and webinars are provided throughout the year based on feedback and data from the annual education.

Workforce members are also provided opportunities for education throughout the year on general and specific compliance issues. A variety of teaching materials, tools, methods, and languages (as necessary) are used to deliver training and education by subject matter experts. Some examples include, but are not limited to:

- 1. Focused Education: As regulatory or other cognizant agencies change requirements; they generally communicate these changes with respect to compliance matters affecting the provision of care/services or billing practices in health care. As needed, education on new guidance or other pertinent topics is provided to target groups using a variety of mediums including email, print, webinars, in-person, and online. For example, the Program spends considerable effort on privacy trainings and requirements.
- 2. Just in Time Education: Providence has implemented various tools to reduce the risks of policy non-compliance. Prior to launching new tools intended to capture at risk behavior, Providence has rolled out extensive education and awareness activities to ensure that the workforce understands the policy expectations and the disciplinary consequences for violating policy. Awareness activities undertaken by Providence to promote compliance with policy include mandatory completion of ad hoc training modules with electronic acknowledgement of new policy; strategically positioned language within systems and applications cautioning the workforce about appropriate use; extensive vetting of technological modifications within systems to promote compliance and enterprise-wide top-down communication from the Chief Executives. These activities are performed by cross-functional areas across Providence striving for a shared culture of compliance that includes, but is not limited to, Clinical Informatics, Human Resources, Digital Innovation, Marketing, and Communications.

Besides these organization-wide trainings, regional and facility level compliance professionals will deliver trainings on specific topics requested from, or deemed necessary for, workforce members at a specific facility or department. These trainings might include revenue cycle compliance, research billing, professional arrangements, EMTALA, etcetera. The documents and educational modules are socialized throughout the workforce and made easily accessible to

workforce members.

Examples of some specific compliance trainings that have been designed and delivered by the Program include:

- Document "When to Call Compliance" providing examples of when to call compliance
- Document "Impermissible Uses of Protected Health Information EHR"
 - Tips on impermissible uses of PHI in the electronic health record.
 - Provides contact information for the Integrity Hotline.
- Document "HIPAA Privacy & Security: What You Need to Know"
 - Tips on the minimum necessary rule, processes within Providence on how to keep patient information secure and contact information for the Integrity Hotline.
- Document "Compliance Handout"
 - Quick, two-sided document that gives eight critical tips on keeping patient information private and secure.
- HealthStream Module "PSJH: RIS Inappropriate Access Electronic Medical Record (EMR) Education
 - 15–20-minute online education which discusses situations of inappropriate access to the EMR and how to appropriately access patient information to prevent inadvertent impermissible access.
 - Discusses relevant policies related to the protection of PHI.
- HealthStream Module "PSJH: RIS Social Media"
 - 10–15-minute online education which discusses inappropriate uses of PHI and social media.
 - Discusses relevant policies related to social media.
- HealthStream Module "PSJH: RIS Appropriate Handling of Physical PHI"
 - 15–20-minute online education which discusses corrective action involving the mishandling or misplacement of physical PHI (discharge summaries, prescriptions, etc.).
 - Discusses relevant policies related to the protection of PHI.
- HealthStream Module "PSJH: RIS Appropriate Verbal Disclosures
 - 10–15-minute online education around the inappropriate and appropriate verbal disclosures of PHI.
 - Discusses relevant policies related to the protection of PHI.
- Compliance SharePoint Site
 - An internal website housing sites for all functions within Compliance to share updates, changes, tools and resources.
- Video Education
 - Several videos going through a privacy investigation, charting in the wrong chart, leaving
 PHI in a locked car, peeking in a medical record, posting PHI on social media.
- Podcasts
 - Privacy in the workplace series: 6-episodes, 3-6 minutes in length.
- Annual Compliance Week activities: Hosted system wide to bring more awareness to the Compliance program, create engagement, and foster relationships with core leaders and caregivers.
- Compliance Champion recognition activities: These take a variety of forms. For instance, in 2021, Program staff targeted workforce members who stood out as "champions of compliance" and sent out over one thousand individual, personalized emails thanking them for their advocacy of a culture of compliance.
- Regional Compliance meetings with education agenda topics (i.e., Compliance Live Forums).
- Live (and recorded) Webinars: twelve different webinars offered per year on topics deemed

higher risk.

- Learn Why and Comply Series: The top six incorrectly answered questions in the current year's compliance Qstream education are discussed in individual videos to deepen the learner's understanding of the topic.
- Monthly Compliance Roadmap: A document shared via the Caregiver Newsletter once a month providing information/updates on a variety of compliance and privacy topics.
- Revenue Cycle Compliance: Creates and distributes "Regulatory Billing & Coding Guidance Clarifications" to multiple Revenue Cycle & Clinical departments and the Department of Legal Affairs proactively and on a case-by-case basis.
- Physician Compliance: Annual Compliance Education Provider Module required via Qstream, separate and distinct educational program on FWA and documentation.
- Research Compliance: Specifically, to protect the rights, welfare, and wellbeing of human subjects involved in research at Providence, Research Compliance Education, in collaboration with numerous other departments, help research staff navigate many of the high-risk areas of research, such as:
 - Human Subjects Protections
 - Research Privacy and Security
 - Conflicts of Interest and Financial Disclosure
 - Conflict of Commitment
 - Research Misconduct
 - Data and Records Retention
 - Research Billing

Additional resources recently developed for support of ongoing research education included:

- Quarterly site training provided upon request
- Specific research compliance topics presented throughout each calendar year
- Microsoft stream channel developed for research compliance education
- Research compliance SharePoint site connected to all past presentations and training offered to the greater research community for ease of viewing
- Continued collaboration with the Providence Human Research Protection Program (HRPP) to ensure continued compliance and provide resources to all researchers

Board and Senior Leader Education

 The Chief Compliance Officer trains Providence Board members on their legally mandated duties annually. This training covers duty of care, duty of loyalty, and duty of obedience. Board members are required to 1) Ask the tough questions and follow-up on progress, 2) disclose situations with potential for conflicts, 3) avoid competition with the organization, and 4) refrain from discussing confidential board business with others.

System • Review aggregate data to identify emerging trends on the horizon • Oversight of Providence Compliance Program • Oversight of Providence Risk Management • Determine pre-emptive actions that will



The Program compliance office collaboratively tracks and trends with business offices and leaders to determine where training and education might be necessary to achieve compliance. In addition, the Chief Compliance Officer is a member of the Providence Learning Council that reviews all training requirements for workforce members to assure that other regulatory training requirements are met.

Regulatory Guidance

Providence will respond appropriately to regulatory guidance, including fraud alerts, issued by various government agencies.

The Office of Inspector General (OIG), Centers for Medicare and Medicaid Services (CMS) and other government agencies periodically communicate regulatory or other guidance with respect to compliance matters affecting the provision of care/services or billing practices in health care. Pertinent information in such guidance will be disseminated to appropriate personnel throughout Providence. When such guidance is issued and where appropriate, the regional compliance office or local ministry will work with department or service line compliance coordinators or management to review local practices and determine whether any action is necessary to achieve compliance. The regional compliance office will collaborate with operations personnel in their respective areas when necessary.

CMS contractors, including fiscal intermediaries and carriers, periodically release bulletins to health care providers. Providence revenue cycle operations monitors these bulletins and implements changes as needed.

Key Policies and Foundational Materials

The Program has established Providence-wide policies, charters, and guidance to define and support the on-going effectiveness of the Compliance Program for Providence.

The Providence-wide policies are posted on the <u>PolicyStat®</u> platform available to all members of the workforce organization-wide. For the most up-to-date version of the policy, please refer to the version posted on <u>PolicyStat®</u>.

Policies and supporting materials directly applicable to this book are listed in the Appendices for internal members of the workforce.

Additionally, Compliance, the Department of Legal Affairs, and other appropriate departments provide supplementary compliance guidance on legal and regulatory compliance through publication of periodic regulatory memoranda and guidelines.

Book 4: Developing effective lines of communication

The OIG's compliance guidance states: An open line of communication between the compliance officer and entity personnel (including contractors and agents) is critical to the successful implementation of a compliance program and the reduction of any potential for fraud, waste, and abuse. Entity personnel should be informed about the ways they can reach the compliance officer directly (e.g., via email, telephone, messaging). This information also should be posted in commonly frequented physical and virtual spaces. The compliance officer may wish to occasionally poll entity personnel on means of reaching the compliance officer to ensure that diverse personnel (including personnel of different generations and communication preferences) have familiar means of communicating with the compliance officer. Entity personnel should be encouraged to bring compliance questions to the compliance officer.

The entity should have at least one reporting path independent of the business and operational functions that permits individuals to report concerns anonymously. This could be through a hotline, a website, an email address, or a mailbox. Options for anonymous reporting should be publicly posted in physical and virtual spaces frequently accessed by entity personnel.

At Providence the maintenance of a process, such as a hotline, to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation is essential to maintaining an effective compliance program.

The purpose of developing open communication is to increase the organization's ability to identify and respond to compliance concerns. Generally, open communication is a product of organizational culture and internal mechanisms for reporting instances of potential fraud and abuse. When assessing the organization's ability to communicate potential compliance issues effectively, Compliance will consider the following factors:

- Has the organization fostered an organizational culture that encourages open communication, without fear of retaliation?
- Has the organization established an anonymous hotline or other similar mechanism so that staff, contractors, patients, visitors, and medical and clinical staff members can report potential compliance issues?
- How well is the hotline publicized; how many and what types of calls are received; are calls logged and tracked (to establish possible patterns); and is the caller informed of the organization's actions?
- Are all instances of potential fraud and abuse investigated?
- Are the results of internal investigations shared with the organization's governing body and relevant departments on a regular basis?
- Is the governing body actively engaged in pursuing appropriate remedies to institutional or recurring problems?
- Does the organization utilize alternative communication methods, such as a periodic newsletter or compliance intranet website?

Open Lines of Communication

Providence fosters and supports a safe, non-threatening environment where individuals may ask questions about integrity and compliance matters and report their concerns. Additionally, Providence utilizes alternative communication methods, such as a periodic newsletter and compliance intranet website.

To support the commitment to its mission, values, and promise, Providence promotes and supports a safe, non-threatening environment that encourages workforce members and others to ask questions and report issues and concerns. Providence provides opportunities that allow anyone to confidentially report issues or concerns to the organization without the fear of retaliation. Workforce members have a right and the responsibility to report any activity they believe may violate laws, regulations, professional standards, or the Code of Conduct.

Providence encourages workforce members to speak first with their immediate manager or supervisor or, in the case of board members, volunteers, contractors, and others, their primary contact for the organization. Workforce members are also encouraged to contact a higher-level manager or seek help through other resources, such as Compliance, their local patient safety event reporting process, or Caregiver Relations in Human Resources. If workforce members are uncomfortable or unsure about how to do this, compliance program staff at the local, regional and system level are available to help. Caregivers and other workforce members can also contact staff in other support functions, such as risk management, legal or human resources - whichever is most appropriate.

Integrity Hotline

Providence has established an organization-wide compliance hotline policy (<u>PSJH-CPP-736</u>) to outline the process for reporting and responding to concerns and allegations against Providence's Code of Conduct, policies, and any relevant regulations. Reports may be made confidentially and without fear of retaliation for reporting concerns in good faith. All workforce members have a duty to report suspected wrongdoing as soon as reasonably possible. This policy establishes one mechanism for such reporting, the *Compliance Hotline* also referred to as the *Integrity Hotline*.

Providence Workforce members have a responsibility to promptly report concerns about actual or potential wrong-doing – including violations of Providence's Compliance Program – through proper channels and are not permitted to overlook such actual or potential wrong-doing.

Workforce members cannot exempt themselves from the consequences of wrong-doing or inadequate performance by reporting such wrong-doing or inadequate performance. However, the consequences of wrong-doing or inadequate performance may not, in any case, be more severe because a workforce member reported it on their own initiative.

Workforce members may report issues and concerns to the toll-free <u>Providence Integrity Hotline</u> (the "Integrity Hotline"). Providence has contracted with a leading provider of hotline and incident management services, to operate the Integrity Hotline. The Integrity Hotline is available 24/7/365 and can be accessed by telephone or <u>online</u>. Individuals may report matters to the Integrity Hotline anonymously if they choose.

Concerns may be submitted:

- Anonymously (a personal identification number to retrieve information about their report is provided when using the Providence Integrity Hotline);
- Confidentially (such requests are honored to the extent allowed by law); or
- Privately (the reporter reveals his/her/their identity and allows it to be used as needed).

Case tracking (the Disclosure Log) is available through the Integrity Hotline by providing reporters with a case identification number they can use to obtain the status or resolution of their issue. Regardless of the reporting method, every effort is made by Compliance to maintain, to the extent allowed by law, the confidentiality of the information reported and identity of the reporter.

All matters reported to Compliance are triaged and assigned for investigation. Upon receipt and review of the reported matter, the Lead Investigator will conduct a preliminary assessment within two business

days of receipt of the disclosure, change the status of the matter to "in process" and triage the matter as appropriate. The results of all investigations are documented and reviewed by Compliance leadership, as appropriate, before closing reports.

Compliance regularly communicates and promotes the availability of the Integrity Hotline and other reporting methods to workforce members through the Code of Conduct, in-person and virtual education and training, newsletters and other publications, the Compliance intranet site, posters, and regular contacts between the compliance liaisons and workforce members.

All hotline investigations of potential and confirmed compliance errors and violations and, as applicable, corrective actions, are documented and maintained in the incident management tracking system in accordance with the Providence Records Retention and Disposal policy.

Retaliation Will Not Be Tolerated

Providence has established an organization-wide non-retaliation policy (<u>PSJH-CPP-733</u>) that strictly prohibits retaliation, retribution, or harassment directed against any workforce member for making a good faith report of their concerns about actual or potential wrong-doing – including violations of Providence's Compliance Program. Providence also prohibits retaliation against any workforce member who assists, in good faith, in the investigation of any reported concern. Any workforce member who engages in such acts of retaliation is subject to discipline, up to and including termination of employment, suspension of medical staff privileges, or termination of business relationships with the organization.

Incidents of retaliation or suspected retaliation stemming from a compliance report may be submitted by workforce members and may be submitted anonymously to the Integrity Hotline. Additionally, concerns about possible retaliation or harassment of any kind may be reported to any compliance office or to human resources. Good faith reports of retaliation or suspected retaliation will be kept confidential to the extent possible, consistent with the need to conduct an appropriate investigation.

Additionally, Providence Human Resources maintains a Harassment Discrimination Retaliation policy on the <u>Caregiver Service Portal</u>, this policy establishes expectations for the work environment and standards for behaviors of all workforce members.

Key Policies and Foundational Materials

The Program has established Providence-wide policies, charters, and guidance to define and support the on-going effectiveness of the Compliance Program for Providence.

The Providence-wide policies are posted on the <u>PolicyStat®</u> platform available to all members of the workforce organization-wide. For the most up-to-date version of the policy, please refer to the version posted on <u>PolicyStat®</u>.

Policies and supporting materials directly applicable to this book are listed in the Appendices for internal members of the workforce.

Additionally, Compliance, the Department of Legal Affairs, and other appropriate departments provide supplementary compliance guidance on legal and regulatory compliance through publication of periodic regulatory memoranda and guidelines.

[Remainder of Page Left Intentionally Blank]

Book 5: Conducting internal monitoring and auditing

The OIG's compliance guidance states: The development of a system to respond to allegations of improper/illegal activities and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations, or Federal health care program requirements. Audits may be conducted by internal or external auditors who have expertise in Federal and State health care statutes, regulations, and Federal health care program requirements.

Effective auditing and monitoring plans help the organization avoid the submission of incorrect claims to Federal health care program payors. Providence develops detailed annual audit plans designed to minimize the risks associated with improper claims and billing practices. Some factors Compliance considers include the following:

- Is the audit plan re-evaluated annually, and does it address the proper areas of concern, considering, for example, findings from previous years' audits, risk areas identified as part of the annual risk assessment, and high-volume services?
- Does the audit plan include an assessment of billing systems, in addition to claims accuracy, in an effort to identify the root cause of billing errors?
- Is the role of the auditors clearly established and are coding and audit personnel independent and qualified, with the requisite certifications?
- Is the audit department available to conduct unscheduled reviews and does a mechanism exist that allows the compliance department to request additional audits or monitoring should the need arise?
- Has the organization evaluated the error rates identified in the annual audits?
- If the error rates are not decreasing, has the organization conducted a further investigation into other aspects of the compliance program in an effort to determine hidden weaknesses and deficiencies?
- Does the audit include a review of all billing documentation, including clinical documentation, in support of the claim?

A comprehensive process is utilized to determine the annual compliance work plan. The Compliance function provides monitoring of key Compliance Program requirements and reports to Providence leadership. In addition, self-monitoring occurs on a regular basis in our facilities, entities, and across service lines.

In addition, regional/business line compliance and risk committees, providers participating in Centers for Medicare and Medicaid Services (CMS) programs, and other functional areas have developed standards and associated self-monitoring operational protocols to assess on-going compliance with applicable laws, rules, waivers, and Providence policies, procedures, standards, and guidelines. When instances of non-compliance are discovered, they are documented, and a corrective action plan is implemented to address the situation.

Providence conducts compliance auditing and monitoring by establishing an annual compliance audit work plan, by determining any areas of risk, as well as utilizing proactive auditing techniques. This ensures that the Compliance Program addresses any areas of concern while sustaining compliance program effectiveness. The Compliance program also works directly with the Internal Audit function to collaborate and build upon Providence's annual Internal Audit Plan.

Systematic, consistent, and organized documentation of audits is executed in the managing of Providence's compliance auditing and monitoring process. The annual compliance audit work plan assists in scheduling, tracking, and managing reoccurring audits. The work plan helps to organize ongoing efforts and is a

valuable resource when conducting annual risk assessments.

Records related to the Compliance Monitoring Program are maintained by the Compliance department in accordance with the Providence Records Retention and Disposal policy.

Compliance Auditing and Monitoring

Monitoring is a base expectation of an effective compliance and ethics program. Monitoring, along with auditing as just described, allows Providence to further identify and act on potential issues before they become larger compliance risks.

Monitoring helps assure Providence management that internal controls are operating effectively. Timely and effective monitoring can help assure internal controls remain robust and in line with an organization's constantly changing risk environment, to prevent potentially costly and damaging internal control failures down the road.

The Compliance Monitoring Program uses monitoring tools and processes to verify that controls management has implemented are working and that business risks are being identified and addressed. In addition to this Program each Providence ministry/department is required to take a proactive role in monitoring and evaluating their work environment, to ensure the procedures within the department follow best practices and follow the laws and policies that govern the work.

An ongoing evaluation process is critical to a successful compliance program. Monitoring provides early identification of program or operational opportunities 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 reviews. Monitoring techniques may include sampling protocols that permit the compliance team to identify and review variations from an established baseline. Significant variations from the baseline should trigger a reasonable inquiry to determine the cause of the deviation.

Accountability for self-monitoring occurs at every level of the organization but particularly by management to help identify if there are areas of compliance risk which should be elevated and/or addressed.

The Compliance Monitoring Program focuses on evaluating effectiveness in accordance with the Office of the Inspector General (OIG) auditing and monitoring guidance and will establish and maintain an effective system for routine monitoring and identification of compliance risks. A three-pronged approach is utilized to execute the compliance monitoring program:

Make a Plan. Implement an annual work plan approved by the Chief Compliance Officer.

Get the Facts. Understand (1) the governing law and the consequences of violating it and (2) the applicable policy, procedure, and/or process.

Know Where to Go. Educate workforce on what to do when a compliance issue arises and how to report it.

By implementing a comprehensive Compliance Monitoring Program, Compliance finds and mitigates potential vulnerabilities, reduces the chance of an external audit, increases policy awareness and alignment, reduces the chance of fraud and abuse, and promotes safe and quality care. The Compliance Monitoring Program establishes standards to ensure that services are conducted in full compliance with Providence ethical standards as well as laws and regulations of federal, state, and local governments.

Monitoring projects are driven by the Compliance annual work plan in addition to ad hoc audits which are conducted to support identified risks that grow out of operational and special needs that span across the system and select regions. While the Compliance Monitoring Program prepares materials for audits and

sometimes conducts audits, every entity/department and facility location where compliance functions are performed within Providence is championed by the Regional Compliance Directors and Compliance Liaisons who help identify a stakeholder/point person in each area of monitoring focus. These regional compliance caregivers work in conjunction with or as support for the point person of the monitoring activity focus.

There are a multitude of approaches that can be taken to implement a monitor. The Program utilizes a combined approach of risk based, regulatory review, and enterprise-wide compliance policies. Its primary function is to provide independent analysis recommendations, guidance, and information concerning compliance related risks that affect the organization. It helps management identify and assess compliance risks and develop recommendations to mitigate risks.

Review Type	Review Type Description	
Client Survey or	The process of discovering whether a department or function is following	
Client Interview	ew current laws, regulations or conditions of participation related to an ider	
	compliance topic or risk area or policy or procedure, and to discover their	
	express and unknown needs and expectations for any new or proposed	
	compliance topics.	
Employee Interview	The determination of caregiver/employer knowledge of, and compliance with,	
	various policies, procedures, and standards.	
Facility Review	ity Review The determination of compliance with data privacy and security and othe	
	facility requirements.	
File Review	Review The evaluation of hard copy documentation (e.g., personnel files, financia	
	records, contracts, etc.)	
Record Review	ecord Review The evaluation of electronic documents (e.g., electronic medical re	
	financial records, contracts, etc.)	
Policy Review	(1) The evaluation of adherence to written policies; and (2) a thorough review	
	of the policy.	
Procedure Review	The evaluation of adherence to written procedures through colleague	
	shadowing.	
Process Review	The evaluation of adherence to written process through colleague shadowing.	
System Review	The evaluation of system access or programming concerns (a.k.a. Desk Review).	

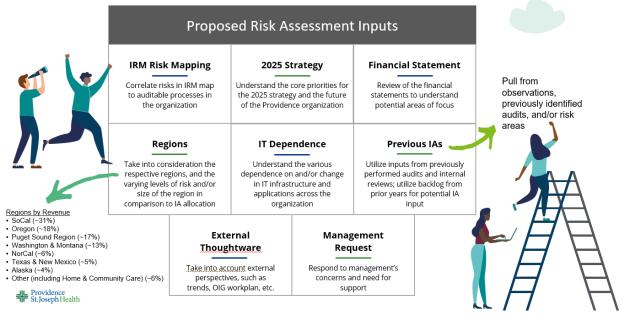
Compliance monitoring activities utilize the following review types:

Internal Audit

Providence Internal Audit is an independent and objective appraisal function that performs evaluations of the organization's operational, clinical, financial, information technology, compliance, and other processes. The results of these evaluations are provided to the Audit & Compliance Committee (ACC) of the Providence Board, as well as Providence leadership to help fulfill their stewardship responsibilities in governing, leading, and managing the organization. This information can be in the form of analysis, appraisals, recommendations, counsel, and other documentation relating to the departments, processes and/or functions reviewed.

The Internal Audit department is led by Providence's Vice President of Internal Audit who reports to the Chief Risk Officer who reports directly to the Audit & Compliance Committee of the Providence Board. The VP of Internal Audit is responsible for developing the annual Internal Audit plan. This plan considers the Providence Integrated Risk Management (IRM) Framework discussed above but also contemplates a number of additional risk inputs. These inputs are illustrated below:

FY23 IA Supplementary Risk Assessment and Planning Inputs



Through the aggregation of all these inputs, internal audit projects are identified that would best cover the observed risks while also considering the amount of annual internal audit resources. The resulting annual plan is then reviewed by the Chief Risk Officer, the executive leadership team and is also reviewed and approved by the Audit & Compliance Committee. The approved audit plan is executed by the "Big Four" professional services firm, Deloitte, under the guidance of the VP of Internal Audit. As the year progresses, the plan is constantly revisited and is subject to change based on emerging risks throughout the year or as priorities change.

The scope of work of the Providence Internal Audit Services department is to determine whether the organization's network of risk management, control, and governance processes, as designed and represented by management, is adequate and functioning appropriately. Examples of activities performed under the scope may include the following:

- Identifying and assessing potential risks to Providence operations;
- Developing an annual audit plan using a risk-based methodology;
- Reviewing the integrity and security of financial, core leader, caregiver, student, resident member and patient information and the systems and operations that produce and maintain such information;
- Reviewing the systems to assure compliance with policies, plans, procedures, laws, regulations, and contractual obligations and evaluating whether the business unit under review is in compliance;
- Reviewing operating, financial, and compliance controls for joint ventures in which Providence has an interest;
- Assessing the means of safeguarding assets and, as appropriate, verifying the existence of such assets;
- Reviewing operations or programs to determine that they are being carried out with appropriate controls;
- Monitoring corrective action plans to ensure appropriate and timely remedial action;
- Conducting ad hoc appraisals, investigations, or reviews as requested by the Board or management;

- Evaluating and assessing significant merging/consolidating functions and new or changing services, processes, and operations, coincident with their development, implementation, and/or expansion;
- Maintaining a professional audit staff with knowledge, skills, experience, and professional certifications to meet the requirements of this charter; and
- Establishing a quality assurance program whereby the chief audit executive assures the proper operation of internal audit activities.

An example of the Internal Audit Plan can be produced upon request, as appropriate.

Revenue Cycle Compliance

A critical auditing and monitoring division of Providence the Revenue Cycle Compliance department. Revenue Cycle Compliance provides coding and billing guidance, assuring Providence is in alignment with continuously changing federal and state requirements. Revenue Cycle Compliance is a risk focused program that utilizes risk-sensing tools to identify and manage risks system wide.

Effective auditing and monitoring plans help Providence avoid the submission of incorrect claims to Federal health care program payors. Revenue Cycle Compliance develops a detailed annual audit plan designed to minimize the risks associated with improper claims and billing practices.

The Revenue Cycle Compliance department supports the entire revenue cycle operational function (registration, patient access, clinical teams, case management, HIM coding, billing offices, customer support ministry leaders, providers, and coders) by partnering with the OIG, CMS, Medicare, and Medicaid assuring correct claims submission.

The purpose of the Revenue Cycle Compliance department is to guide provider and hospital billing practices to adhere to and comply with regulatory requirements assuring Providence receives proper payments, by providing proactive internal coding and billing audits.

This team creates and distributes "position papers" referred to as "Revenue Cycle Compliance Clarification Documents". These documents are created in response to new and existing regulatory coding and billing rules/requirements and are communicated to multiple Revenue Cycle, Clinical, and Operational departments appropriately, proactively, and on a case-by-case basis.

Revenue Cycle Compliance caregivers reference these documents as a foundational repository to streamline research efforts and to stay on top of the ever-changing Regulatory Guidance. These documents are routinely updated with the required standard format of including the actual/pertinent links to the CMS regulation for 1) accuracy of facts 2) to encourage our Clinical and Billing Office to engage in staying current.

This proactive program provides clarification of billing/coding/documentation rules, audits, and coordinates refunds of any overpayments received in error following the Voluntary Self-Disclosure of Overpayments Received in Error, following the CMS 60 - Day Overpayment Rule (CMS 6037- F Final Rule).

The Revenue Cycle Compliance division provides a broad scope of compliance reviews on an annual basis including:

- New Coder Validation Auditing for all Professional, Hospital, and specific External Coders. This is a co-sourced model with leading vendors in coding accuracy and compliance.
- **Professional billing, coding and documentation audits** are performed on new providers within thirty days of employment with an established threshold success rate. Additional provider audits are performed based on specific billing and documentation risks or requirements, various legal reviews, Integrity Hotline issues, ministry audit requests, ad

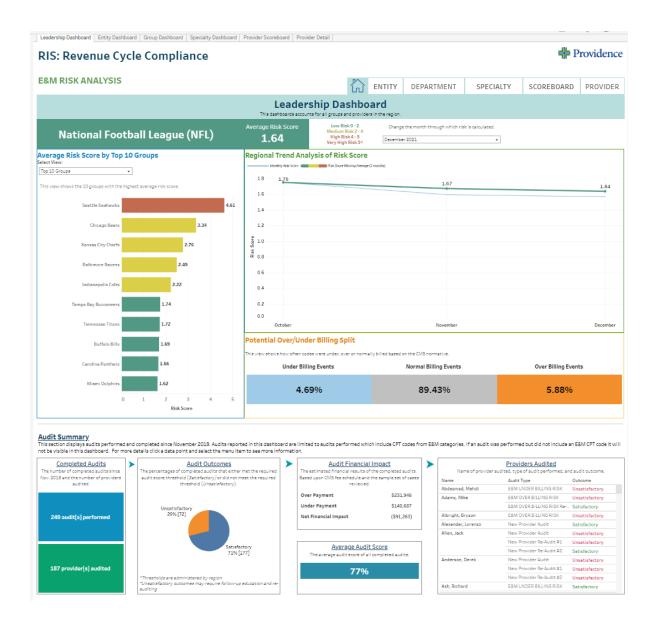
hoc requests, and internal proactive review including Public Health Emergency (PHE)/COVID related risks, 2021 Evaluation and Management (E&M) Level changes etc.

- Hospital Audits are performed at various ministries based on the following: Integrity Hotline issues, ministry audit requests, legal reviews, ad hoc requests, and internal proactive reviews including PHE/COVID related risks, Important Message from Medicare (IMM), Medicare Outpatient Observation Notice (MOON), Appropriate Use Criteria (AUC)Protecting Access to Medicare Act (PAMA), Two Midnight Rule, Inpatient Rehabilitation Facilities (IRF), Cataract Removal Procedures etc.
- Quality Assurance Reviews of our external auditing vendors.
- **Compliance oversight of external regulatory agencies** such as: OIG, CMS, Recovery Auditors (RACs), Medicaid auditors and other regulatory audit findings as processed by the divisions of Revenue Cycle and Physician Enterprise.
- **Coder validation audits** focus on a program of reviewing internal and external hospital and professional coders utilizing a co-sourced model to analyze coder accuracy rates across the system.

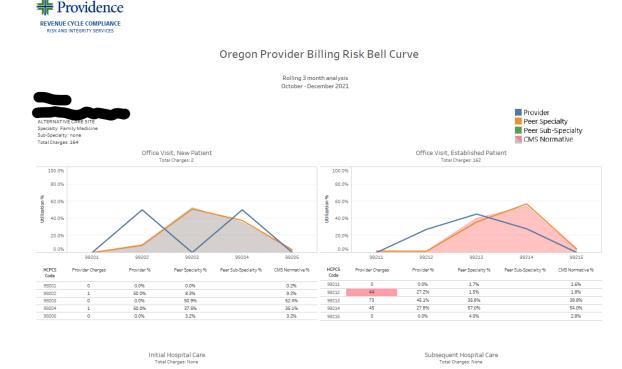
Newly implemented techniques and risk assessment software is affording Revenue Cycle Compliance to develop and implement a continuous risk assessment process. A newly acquired software program is MDaudit[®]. Samples of the dashboards and work done by this process shall be made available for inspection as requested to appropriate parties.

MDaudit[®] is a risk-intelligent solution that tracks, trends, and compares billings to an internal benchmark and to Medicare's national averages by medical specialty. Utilization of MDaudit[®] enables the Revenue Cycle Compliance Department to monitor risk, detect anomalies, and automate auditing workflows. While MDaudit is not a full-scale Data Analytics/Mining tool, it provides the Revenue Cycle Compliance Department with good insight into Provider billing patterns and billing risks by continually assessing data to identify trends for focused review.

Feedback from the Operations teams indicated the need for better data and insight into E&M risks. The Revenue Cycle Compliance Department designed and built two new tools to help the Providers understand their individual risk and help Leadership understand and manage risk in their Regions. The first tool is the leadership dashboard regarding our E&M risk analysis.



The second tool is our E&M Bell Curve SharePoint which compares a Providers E&M billing patterns with CMS Normative.



Together these tools give Operations Leadership visibility into the types of risk we monitor in Revenue Cycle Compliance and provide insight into the Audits that have been completed.

Another auditing tool utilized by Revenue Cycle is the CMS Program for Evaluating Payment Patterns Electronic Report (PEPPER) as a comparative data report that provides hospital-specific Medicare data statistics for discharges vulnerable to improper payments. PEPPER supports Providence's Revenue Cycle Compliance by summarizing provider-specific Medicare data statistics for target areas often associated with Medicare improper payments due to billing, Diagnoses Related Groups (DRG) coding and/or admission necessity issues. Target areas are determined by the CMS.

PEPPER supports Providence's Revenue Cycle Compliance efforts by providing three years of data statistics for each of the CMS target areas, comparing performance to that of other hospitals or facilities in the nation, specific Medicare Administrative Contractor (MAC) jurisdiction and state. PEPPER is also utilized to compare data statistics over time to identify changes in billing practices, pinpoint areas in need of auditing and monitoring, identify potential DRG under or over-coding problems and identify target areas where length of stay is increasing. PEPPER is also being used to assist Providence achieve CMS' goals of reducing and preventing improper payments.

Research Billing Compliance

The Clinical Research Billing Compliance Program (CRB Program) assists the system in monitoring risk controls to mitigate erroneous billing to health insurance during the complex setting of clinical research. The CRB Program undertakes training and education on relevant rules for clinical research billing and provides targeted training as necessary for corrective actions and localized risks. The CRB Program undertakes compliance auditing to assess the sufficiency of centralized system operations and local identified risks.

Research Billing Compliance leadership is present and available as an expert knowledge resource to answer regulatory and compliance questions from operations for managing risk scenarios. We triage

clinical research compliance and billing questions from around the system as to whether they are appropriate compliance questions, or better answered by operations as business decisions, or rise to a risk level in which we need to collaborate with Legal to address potential risk.

Providence is currently undertaking a multi-year re-organization of clinical research billing processes, which accordingly makes our Office iterative until processes are fully deployed. During the system centralization of research billing, we encourage the Office of Research Administration to develop and maintain policies and procedures that provide consistency across the system as to how research billing is conducted.

Research Billing Compliance has provided extensive research billing compliance training across the system which assisted in the centralization of the Office of Research Administration. Research Billing Compliance is planning further educational opportunities as the system-wide processes are standardized.

A significant amount of the Office's work has recently involved two types of auditing:

- For Cause When concerns or issues are raised and brought to our attention, the Research Billing Compliance Office investigates and deploys resources to address any issues raised which are within the scope of the Office. Once addressed, the Office then assists in the remediation of issues raised, i.e., billing concerns, staffing, training with appropriate assignment of corrective actions to operations. The Office communicates with the leadership of the entity/facility the ongoing process of improvement of the addressed issues.
- Not-For-Cause The Office, on an on-going basis, has begun the process of compliance auditing for clinical research billing operations based on risk. The Office develops teams to assist in the audit with process and outcome.

Excluded Individuals & Entities

Federal and state laws prohibit Providence from employing or contracting with organizations or any individual who has been excluded from participation in government programs. Compliance regularly reviews published information to check for excluded organizations and individuals. While individuals or entities are excluded, they cannot be a Providence caregiver/employee, provider, volunteer, student, Board member, or vendor (collectively referred to as workforce members).

Workforce members are required to notify human resources, the facility's regional compliance manager or the Providence Compliance Office if they receive notice that they will be or have been excluded from participation in any federal or state program.

Providence will not bill for services ordered, rendered, or supervised by an organization or individual that is excluded, suspended, debarred, or ineligible to participate in a federal health program, or has been convicted of a criminal offense relating to the provision of health care items or services and has not been reinstated in a federal health care program.

Additionally, Providence will notify the appropriate government agency and impacted Health Plan partners within 5 business days of discovery of a confirmed System for Award Management (SAM) or Office of Inspector General (OIG) sanction or exclusion. Providence will maintain evidence of notifying Health Plan partners within 5 business days of discovery of a confirmed SAM or OIG sanction or exclusion. Providence will also, notify impacted Health Plan partners if SAM or OIG sanctions or exclusions are lifted for individuals that are rehired.

Exclusion Screening

An exclusion record identifies individual, entities, and parties excluded from receiving Federal funds, Federal contracts, certain subcontracts, and certain types of Federal financial and non-financial assistance and benefits. Exclusions are also referred to as suspensions and debarments in some instances.

The OIG has the authority to exclude individuals and entities from Federally funded health care programs for a variety of reasons, including a conviction for Medicare or Medicaid fraud. The OIG maintains a list of all currently excluded individuals and entities called the List of Excluded Individuals/Entities (LEIE). Anyone who hires an individual or entity on the LEIE may be subject to civil monetary penalties (CMP). To avoid civil monetary penalties, Providence must routinely check this list.

Providence has developed a robust, standardized process for monitoring exclusions and sanctions on various "excluded individual" lists by utilizing an external organization, Streamline Verify[®]. On a monthly basis newly hired caregivers, current caregivers, medical staff, vendors, and volunteers are run through the exclusion screening process. Foundation members are also run through this system. These individuals are screened against numerous exclusions lists and databases, including but not limited to: OIG-List of Excluded Individuals and Entities (LEIE), U.S. General Services Administration (GSA-SAM), Office of Foreign Assets Control OFAC, Specially Designated Nationals and Blocked Per (SDN), Centers for Medicare and Medicaid Services (CMS) Preclusion, Medicare Opt-Out, and state exclusion lists where they exist.

The Compliance Monitoring Program conducts the monthly exclusion screening processes. There are separate exclusion screening process flows for employees, global partners, vendors, and members of the medical staff. Per Providence policy, if an individual or entity is found to be on one of the exclusion lists, an investigation procedure is followed to ensure that the match is confirmed or ruled out by utilizing specific personal data points (SSN, DOB, NPI, license number, etc.). If an individual is confirmed to be on an exclusion list, the appropriate policy, determined by the individual's relationship to the organization, will be followed.

Additionally, Compliance works with internal leadership, Human Resources, Legal Affairs, Supply Chain, Purchasing, Accounts Payable, and other offices as appropriate to review potential matches on any exclusion list.

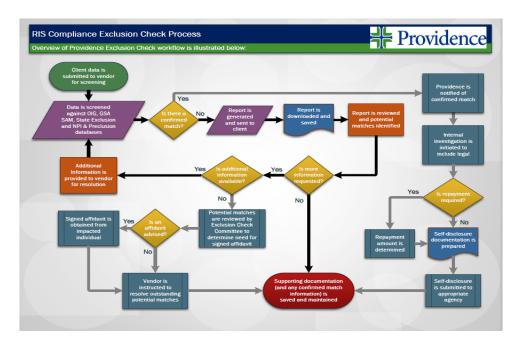
Providence maintains the following exclusion screening policies for caregivers/employees, medical staff, and vendors.

- Background Check and Excluded Individuals policy on the Caregiver Service Portal
- <u>PSJH-GOV-217</u> Background Check for System Board of Directors, Community Governance, and Foundation Boards
- <u>PSJH-MED-308</u> Excluded Individual Checks Medical Staff
- <u>PSJH-REH-1005</u> Excluded Individual and Entities Checks Vendors

The records related to the status and results of the monthly exclusion screenings is maintained by Compliance in accordance with the Providence Records Retention and Disposal policy (<u>PSJH-CPP-715</u>) and shall be made available for inspection as requested to appropriate parties.

The process for exclusion and sanction screening, review, and final determination is included below.





Proactive Privacy Monitoring Program Overview

When patients, including ourselves and our families, entrust Providence with their protected health information at the point of care, they expect their information to be safeguarded and accessed for legitimate patient care and business reasons. Effective privacy and security practices are essential to Providence's continued modernization and in satisfying the expectations of our patients.

The Compliance Office uses Protenus[®], a tool that automates monitoring of users of Providence's electronic medical health (EHR) systems. Protenus is a predictive analytics software platform that interfaces with our EHR and analyzes who may have inappropriately accessed records. Protenus provides for much greater visibility into user activity within patient care systems and applications creating a high reliability. The technology provided through Protenus further enhances the efficiency and effectiveness of existing monitoring programs so that suspected impermissible access is detected in a timely manner.

The system creates alerts when security features such as "Break the Glass" or confidential patient flags are impermissibly bypassed and when other types of suspicious activity is identified. The Privacy team is flagged of possible "risks" and then investigates any potential breaches of privacy (like they would with current privacy issues/complaints/allegations). In turn, the privacy team works collaboratively with caregiver relations to investigate questionable access and to ensure that appropriate corrective action and sanctions are applied, as necessary.

Through the utilization of Protenus, Providence can:

- Provide real-time detection and proactive alerting of impermissible access to Protected Health Information by electronic medical record users in our regions
- Provide for expedited reactive access investigations by Privacy
- Rapidly identify unusual access patterns with machine learning intelligence
- Work with a consistent team of privacy caregivers to expertly identify, investigate, and mitigate potential incidents.

In all cases, when instances of non-compliance are discovered, they are documented, and corrective action is implemented by management to mitigate the risk and/or resolve the risk. Education and/or policies and procedures may be developed and/or revised based on the nature of the non-compliance. Ongoing monitoring will provide assurance that the mitigation activities are successful.

Key Policies and Foundational Materials

The Program has established Providence-wide policies, charters, and guidance to define and support the on-going effectiveness of the Compliance Program for Providence.

The Providence-wide policies are posted on the <u>PolicyStat®</u> platform available to all members of the workforce organization-wide. For the most up-to-date version of the policy, please refer to the version posted on <u>PolicyStat®</u>.

Policies and supporting materials directly applicable to this book are listed in the Appendices for internal members of the workforce.

Additionally, Compliance, the Department of Legal Affairs, and other appropriate departments provide supplementary compliance guidance on legal and regulatory compliance through publication of periodic regulatory memoranda and guidelines.

[Remainder of Page Left Intentionally Blank]

Book 6: Enforcing standards through well-publicized disciplinary guidelines

The OIG's compliance guidance states: The organization should establish and publicize its procedures for identifying, investigating, and remediating (including re-training or discipline for the involved individuals) actions that do not comply with the entity's standards of conduct, policies and procedures, or Federal and State law. This can be accomplished using audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem area.

To deter noncompliant conduct, the consequences of noncompliance should be consistently applied and enforced. All levels of employees should be subject to the same consequences for the commission of similar offenses. The commitment to compliance applies to all personnel levels within an entity, including contractors and medical staff.

By enforcing disciplinary standards, Providence helps create an organizational culture that emphasizes ethical behavior. Providence works to ensure that (1) disciplinary standards are well publicized and readily available to all members of the workforce; (2) Disciplinary standards are enforced consistently across the organization; (3) each instance involving the enforcement of disciplinary standards IS thoroughly documented; and (4) workforce members are screened routinely against government sanctions lists, including the OIG's List of Excluded Individuals/Entities (LEIE) and the General Services Administration's Excluded Parties Listing System.

Providence workforce members are expected to conduct themselves with integrity. All workforce members are responsible for their actions and are expected to know and understand their responsibilities in following Providence policies, procedures, standards, and guidelines. Workforce members have a duty to report, if they know, or should have known, about a violation of law, regulation, or policy.

Any Providence workforce member who violates federal, state, or local laws, regulations or Providence policy, procedure, standard or guideline is subject to disciplinary action in accordance with established policies. This action is determined according to the nature of the violation, case-specific considerations, and the individual's work performance. Corrective action plans are designed to assure that specific violations are appropriately addressed and resolved. Supervisors and others, as appropriate, develop and implement a corrective action plan and monitor it as needed to resolve concerns.

While determining appropriate discipline, supervisors may consult with additional Providence resource experts, such as Human Resources, Compliance, or the Department of Legal Affairs. Supervisors are responsible for documenting discipline in accordance with Providence policy.

Providence, through its regional and ministry-specific policies will impose appropriate sanctions for noncompliance with policies and/or applicable international laws, federal, and/or state regulations up to and including termination.

Providence is committed to consistent application of the sanctions established in the organization's policies. Providence will investigate all alleged violations and base corrective action on the facts, circumstances, and severity of a substantiated violation. When necessary, Providence will impose appropriate corrective actions for violations, up to and including termination. All corrective actions that are applied must be documented according to the applicable Human Resources policies and collective bargaining agreements.

All Providence ministries, including non-healthcare entities and affiliated entities, have well-publicized disciplinary standards readily available to workforce members. Providence has organization-wide

corrective action policies that guide disciplinary actions within the ministries. Disciplinary standards are publicized to all workforce members via the annual compliance education and the Code of Conduct policy.

- <u>PSJH-CPP-851</u> Privacy Sanctions
- Counseling and Corrective Action policy on the Caregiver Service Portal
- <u>PSJH-CPP-735</u> Compliance Investigations

Corrective Action

Where an internal investigation substantiates a reported violation, Providence will initiate corrective action, including, as appropriate, refunding overpayments, notifying the appropriate government agencies, taking disciplinary action and/or implementing other corrective actions to prevent a similar violation from occurring in the future.

Corrective Action Plans

Corrective action is determined by management with consultation and advice from Human Resources, Compliance, and the Department of Legal Affairs, according to the nature of the compliance or integrity violation, case-specific considerations, and the individual's work performance.

Corrective action plans are designed to ensure that specific violations are appropriately addressed and resolved. Management is responsible for the development and implementation of corrective action plans and is required to monitor to assure issues addressed are resolved. Compliance will periodically monitor or audit an area of concern raised to ensure it has been resolved.

Corrective action plans will include the following elements, as appropriate:

- Ceasing the non-compliant practice;
- Reporting to the appropriate governmental authorities and/or affected individuals within required timeframes;
- Refunding overpayments to the appropriate parties within established timeframes;
- Providing recommendations when appropriate;
- Instituting preventative measures including, without limitation, remedial training, and education;
- Determining whether the root cause is systemic; and
- Monitoring the corrective action.

Enforcement of Compliance Policies

Workforce members who commit compliance or privacy violations will be investigated and recommended for sanctions based on the level of the violation, as proscribed by policies. The level of violation will be determined by management with consultation and guidance from Human Resources according to the severity of the violation, whether the violation was intentional or unintentional, the impact or influence of the event on the patient, the risk impact to Providence, and/or whether the violation indicates a pattern or practice of violations.

Other mitigating and escalating factors may be considered as determined by the core leader in conjunction with Human Resources and Compliance. Any sanction imposed on workforce members will be in accordance with the Levels of Violation (below) and applicable Human Resources policies.

Levels of Violations

Level One – Unintentional Violation: A violation will be classified as a Level One when it results from
a situation where a workforce member was not expected to have knowledge on a certain topic, or

the policy violation results from unintentional human error, and the workforce member has not had any previous Level One violations. Generally, a level one violation is a first or one-time occurrence.

- Level Two Intentional Violation: A violation will be classified as Level Two when it is deemed of low to moderate risk and results from a situation where a workforce member knew, or reasonably should have known, the practice or action is in violation of policy. A Level Two violation also may result when a workforce member repeats a Level One violation after being made aware of the policy requirements.
- Level Three Intentional Violation: A violation will be classified as Level Three when it is deemed of significant risk and is the result of a deliberate action by a workforce member where the workforce member knew, or reasonably should have known, that the practice or action is a violation of Providence privacy and/or security policies. A Level Three violation also may result when a workforce member repeats a Level One or Level Two violation after being made aware of the policy requirements.

Escalating and mitigating factors that impact sanctions for Level One and Level Two Violations may include the following:

Escalating Factors:	Mitigating Factors:
 Nature, severity, and frequency 	 Significant period of time since last violation
 Relationship of offense to workforce 	 Technical or inadvertent error
member's position	 No prior disciplinary history
 Prior disciplinary history 	 No pattern of similar offenses
 Brief period of time since the last violation 	 No evidence that the violation was grossly
 Pattern of similar violations or number of 	negligent
total violations	 Systemic issues resulting in impossibility to
 Evidence that the violation was grossly 	comply with policy
negligent	 Minimal impact to Providence operations,
 Impact to Providence operations, workforce 	workforce, clients, persons served
clients, persons served	 The potential for re-education
Impact on the health and safety of workforce	2,
clients, persons serviced	

Consistency and standardized sanctions are critical to promoting trust and fairness within Providence. A coordinated role between Compliance and Human Resources promotes the effectiveness of policy-based sanctions.

Key Policies and Foundational Materials

The Program has established Providence-wide policies, charters, and guidance to define and support the on-going effectiveness of the Compliance Program for Providence.

The Providence-wide policies are posted on the <u>PolicyStat®</u> platform available to all members of the workforce organization-wide. For the most up-to-date version of the policy, please refer to the version posted on <u>PolicyStat®</u>.

Policies and supporting materials directly applicable to this book are listed in the Appendices for internal members of the workforce.

Additionally, Compliance, the Department of Legal Affairs, and other appropriate departments provide supplementary compliance guidance on legal and regulatory compliance through publication of periodic regulatory memoranda and guidelines.

Book 7: Responding promptly to detected offenses and undertaking corrective action

The OIG's compliance guidance states: Compliance programs should include processes and resources to thoroughly investigate compliance concerns, take the steps necessary to remediate any legal or policy violations that are found, including reporting to any Government program agencies or law enforcement where appropriate, and analyze the root cause(s) of any identified impropriety to prevent a recurrence. How an entity responds when it finds a violation resulting in a substantial overpayment or serious misconduct sets apart those that have a strong compliance program from those with a compliance program that is more form than substance.

Additionally, the compliance officer should oversee investigation and remediation of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals.

By consistently responding to detected deficiencies, Providence can develop effective corrective action plans and prevent further losses to Federal health care programs. Providence responds to detected deficiencies by assuring that (1) all reported matters are thoroughly and promptly investigated; (2) corrective action plans developed that take into account the root causes of each potential violation; (3) periodic reviews of problem areas are conducted to verify that the corrective action that was implemented successfully eliminated existing deficiencies; (4) when a detected deficiency results in an identified overpayment to the hospital, overpayments are promptly reported and repaid to the Fiscal Intermediary; and (5) if a matter results in a probable violation of law, the matter is promptly disclosed to the appropriate law enforcement agency.

Providence has established policies and procedures for promptly responding to potential compliance issues, including issues reported to compliance through the hotline or directly to a compliance staff member, identified through internal audits, and identified through government audits and investigations. Where audits or investigations involving compliance matters result in identified issues or errors, Providence ensures appropriate corrective actions are timely taken, including, as may be necessary, the timely processing of repayments to federal and state health care programs. Providence policies require workforce members to cooperate with any internal or government investigation and prohibit workforce members from destroying or altering documents requested as part of an investigation. Providence has also established policies for the retention of records in connection with legal and regulatory investigations.

Providence has also established an Investigation Unit within the Compliance Department that is specifically tasked with reviewing, leading, and coordinating complaints and conducting independent investigations as needed. Compliance works closely with the investigation unit, the department of legal affairs, functional areas, or external resources, as appropriate, in responding to and fully assessing potential errors or violations.

Violations and errors involving government health care program requirements and other applicable federal and state laws and regulations may be identified through a variety of sources, including routine internal auditing and monitoring, reports from workforce members, government audits and investigations, and contacts from other third parties (such as payers, government contractors, suppliers and vendors, and others).

Investigation Process

Violations of an entity's compliance program, failures to comply with applicable Federal or State law, and other types of misconduct threaten an entity's status as a trustworthy organization capable of

participating in Federal health care programs and the health care industry. Detected but uncorrected misconduct can seriously endanger the mission, reputation, and legal status of the entity.

Providence has established an organization-wide Compliance Investigations policy (<u>PSJH-CPP-735</u>). The purpose of this policy is to provide requirements to the investigation process for internal investigations of allegations against PSJH's Code of Conduct, policies, and any relevant regulations; gathering facts and engaging other resources as appropriate; determining whether the allegations are substantiated; and identifying ways to address issues and/or mitigating risks as appropriate. Additionally, investigations are used in protecting PSJH's assets; protecting the reporter to the extent possible; minimizing workplace disruption; avoiding unnecessary litigation; and answering regulatory inquiries.

When a report of a potential violation or error is received, the Investigation Unit coordinates with Compliance to first triage, categorize, and assign a lead investigator to the matter. Upon receipt and review of the integrity matter, the Lead Investigator will conduct a preliminary assessment within two business days of receipt of the disclosure, change the status of the matter to "in process" and triage the matter as appropriate. The Lead Investigator will conduct an initial review to confirm whether a violation or error may have in fact occurred. This usually requires the assistance of the functional area(s) involved with the potential violation or error. If, however, the report includes allegations of knowledge or intent on behalf of management or personnel in the area, the investigator will conduct a preliminary review without the involvement of the functional area(s), to the extent possible. As appropriate, the investigator will consult with Providence legal counsel and other functional areas (such as billing, coding, quality and patient safety, medical leadership, research, pharmacy, lab, etc.) to fully assess the potential violation or error.

Some violations may be so serious that they warrant immediate notification to governmental authorities, prior to, or simultaneous with, commencing an internal investigation. This includes conduct that:

- is a clear violation of criminal law;
- has a significant adverse effect on either patient safety or the quality of care provided to patients (in addition to any other legal obligations regarding quality of care or abuse or neglect); or
- indicates evidence of a systemic failure to comply with applicable laws, an existing CIA, or other standards of conduct, regardless of the financial impact on Federal health care program.

Corrective Actions

According to the OIG: Once the entity has gathered sufficient credible information to determine the nature of the misconduct, it should take prompt corrective action, including:

- refunding of overpayments;
- enforcing disciplinary policies and procedures; and
- making any policy or procedure changes necessary to prevent a recurrence of the misconduct.

If the entity determines that the misconduct resulted in an overpayment, it should promptly repay the overpayment to affected government agencies. Federal law requires entities repay any overpayments received from Medicare or a State Medicaid program within 60 days after identification. The entity should follow and enforce its policies and procedures against responsible individuals, including those in leadership or supervisory roles whose neglect or reckless disregard of their duties allowed the misconduct to occur unchecked or prevented the entity from identifying the misconduct earlier.

If the completion of a review or investigation confirms the existence of a violation or error, Compliance

will obtain assistance from the Department of Legal Affairs, relevant functional areas, or external resources, as appropriate, to determine the impact of non-compliance with federal and state laws and regulations (including federal and state health care program reimbursement requirements) and the extent of corrective actions needed.

Management with responsibility over the impacted area are responsible for developing corrective action plans that address the "root cause" of the error or violation. Corrective action plans include timely completion dates for activities, such as additional education and training, changes to control or processes, timely refunds of overpayments (e.g., within 60 days), and/or disciplinary action of caregivers, as may be appropriate.

In cases of violations or errors that are the result of systemic defects in operating procedures or controls, significant pattern of similar errors, or have the potential for substantial repayment liabilities to federal or state health care programs, a formal corrective action plan will be prepared. Compliance in coordination with the Department of Legal Affairs and other members of the review team, will determine the extent of additional corrective actions that may be necessary, including notification to federal or state health care contractors; the determination and reprocessing of repayments, and/or disclosures to federal or state regulatory agencies. Compliance and the Department of Legal Affairs will approve the final corrective action plan. Compliance in coordination with Department of Legal Affairs, appropriate senior leaders, and applicable compliance committee will provide oversight in helping ensure commitments under the corrective action plan are timely met.

Documentation

Regardless of the size or severity of the violation being investigated, a contemporaneous record of the investigation should be maintained, so that a record of the investigation can be compiled. The record should include:

- documentation of the alleged violation;
- a description of the investigative process;
- copies of interview notes and key document;
- a log of the witnesses interviewed, and the documents reviewed;
- the results of the investigation; and
- any disciplinary action taken, or corrective action implemented.

All reviews and investigations of potential and confirmed compliance errors and violations and, as applicable, corrective actions, are documented and maintained in the Investigation Unit's incident tracking system.

Key Policies and Foundational Materials

The Program has established Providence-wide policies, charters, and guidance to define and support the on-going effectiveness of the Compliance Program for Providence.

The Providence-wide policies are posted on the <u>PolicyStat®</u> platform available to all members of the workforce organization-wide. For the most up-to-date version of the policy, please refer to the version posted on <u>PolicyStat®</u>.

Policies and supporting materials directly applicable to this book are listed in the Appendices for internal members of the workforce.

Additionally, Compliance, the Department of Legal Affairs, and other appropriate departments provide supplementary compliance guidance on legal and regulatory compliance through publication of periodic regulatory memoranda and guidelines.

Book 8: Ongoing risk assessment

The OIG's compliance guidance states: *Risk assessment is a process for identifying, analyzing, and responding to risk. A compliance risk assessment is a risk assessment process that looks at risk to the organization stemming from violations of law, regulations, or other legal requirements. For entities participating in or affected by government health care programs, a compliance risk assessment focuses on risks stemming from violations of government health care program requirements and other actions (or failures to act) that may adversely affect the entity's ability to comply with those requirements.*

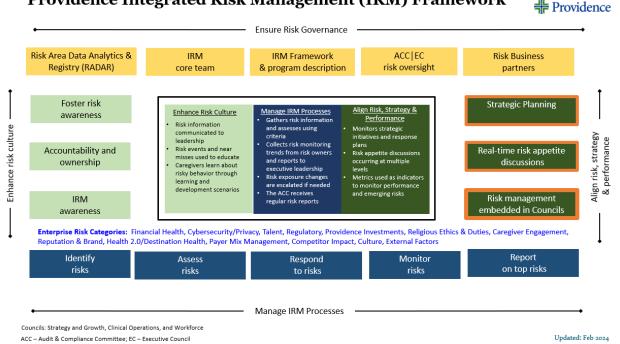
Periodic compliance risk assessments should be a component of an entity's compliance program and should be conducted at least annually.

Risks are inherent in business activities as these activities relate to strategic goals, business performance, and compliance with laws and regulations. As part of an effective compliance program, Providence implements a dynamic risk assessment process that includes ongoing identification. Providence's Integrated Risk Management (IRM) assists the organization and its affiliates to identify and manage key risks across 13 categories and evaluate emerging and strategic risks to protect and create value. Categories include risks that could impact Providence's brand and reputation, operations, finance, regulatory compliance, legal, geo-political, cultural, religious, and/or ethical matters.

Providence understands that risks occur in real time, the best time to assess them. Risk identification starts with an understanding of the strategies, priorities, challenges, and market impact. Risk appetite is identified based on industry, culture, and business variables. Next, risk implications of potential initiatives, business decisions and cultural changes are identified. Risks are assessed through focused discussions, interviews, risk surveys, and listening. Executive Council participates in prioritizing the enterprise risks by assessing them based on *Impact* (how severe are the consequences to the organization if the risk materialized) and *Vulnerability* (how susceptible is the organization to the risk) to determine the risk intensity.

In addition, sources of information such as government reports and emerging regulations are supplemented with internal data analysis including hotline calls or other internal reports of concerns, information from tools and technology to proactively identify emerging risks, risks pertinent to geo zones, cross industry and international. When risks are identified to exceed the risk tolerance of the organization, IRM works with management, executive leadership, and the Board of Directors to assure appropriate action is taken to mitigate the risk. The Providence Executive Council provides guidance and oversight of risk priorities and mitigation. Significant risks are shared with the Board Audit and Compliance Committee (ACC) at quarterly meetings.

The integrated risk management process is used by Compliance to build the annual Compliance Work Plan. Compliance leadership is acutely aware that risk assessment and risk identification must be dynamic with the premise that risks occur in real time. As such, the auditing and monitoring function within the Compliance Program collaborates with IRM and the Internal Audit, Revenue Cycle, Research, Physician Enterprises, and each ministry in the system to identify a plan based on the dynamic risk assessment process and identified risk areas which are then implemented. This plan may change based on risks of the organization's strategies, priorities, challenges, and market impact. The annual Compliance Work Plan is augmented, changed, or adapted as needed as emerging risks are identified and approved by the Board ACC.



Providence Integrated Risk Management (IRM) Framework

Throughout the risk assessment and compliance auditing and monitoring plans, several guiding principles are incorporated. They are as follows:

- Risks link to Providence's strategic and operational objectives and value drivers at the local, regional, and line of business level
- Activities are harmonized across all the risk management groups (Compliance, Cybersecurity, Internal Audit, Quality, Revenue Cycle, Finance, etc.)
- A common risk governance structure is used across the system
- Continuous top-down and bottom-up risk identification
- Proactive resilience and traditional risk management
- Support of the Mission, Values, and Vision of Providence

Work Plan Development

The annual risk assessment process generally begins in August and leverages the IRM dynamic risk assessment process described above. As work plans are developed by Internal Audit and Compliance, additional risks may be identified that may not rise to the level of severity or significance of being included on the enterprise risk profile/placemat.

Compliance takes the more comprehensive list of risks and working with Compliance leadership, each risk is assessed using a scale of Highest Priority (1) to Lowest Priority (5) to develop draft work plans for compliance and internal audit. Other factors, that are considered, are Compliance staff expertise to conduct the project, coverage by another Providence function and available staff hours to assign to projects.

The draft work plans are then socialized with the Chief Compliance Officer and Senior Leadership. Once the Chief Compliance Officer has obtained this additional input, the work plans are finalized and presented for approval to the Audit and Compliance Committee of the Board. These work plans are dynamic and updated as new and emerging risks are identified and management requests are received.

Compliance Supplementary Risk Assessment and Planning Inputs



Compliance Work Plan Development Process



The resulting work plans identify compliance monitoring and internal audit work projects, which in turn may require added specific risk assessments to provide a focused scope for the project. Additionally, work plans may result in the implementation of system-wide standards and other compliance monitoring and internal audit projects.

The compliance work plan organizes the risk areas and what the compliance program will do to evaluate operations relative to that risk. Compliance is not Operations and does not perform their work, but rather is independent and objective of Operations. Instead, the compliance program identifies areas of risk and determines if the risk is well controlled, or if there are gaps or noncompliance occurring regarding the risk. Each of the prioritized risk areas is evaluated for gaps, noncompliance, and for how best to test

compliance within that risk area. This can be accomplished through a controls assessment, testing, a probe audit, or other appropriate method based on the risk.

For all work performed as part of the work plan, Compliance will ensure that project materials are (1) consistent and thoroughly documented; (2) organized and stored in a way that is can be easily found in the future, and (3) retained in accordance with the Providence Record Retention and Disposal (<u>PSJH-CPP-715</u>) policy.

Key Policies and Foundational Materials

The Program has established Providence-wide policies, charters, and guidance to define and support the on-going effectiveness of the Compliance Program for Providence.

The Providence-wide policies are posted on the <u>PolicyStat®</u> platform available to all members of the workforce organization-wide. For the most up-to-date version of the policy, please refer to the version posted on <u>PolicyStat®</u>.

Policies and supporting materials directly applicable to this book are listed in the Appendices for internal members of the workforce.

Additionally, Compliance, the Department of Legal Affairs, and other appropriate departments provide supplementary compliance guidance on legal and regulatory compliance through publication of periodic regulatory memoranda and guidelines.

[Remainder of Page Left Intentionally Blank]

Appendix A: Key Policies Supporting the Program

Listed below are the policies supporting the Compliance Program in effect as of the approval date of the active Compliance Program Description document. Policies may be added, revised, or retired over time; names and numbers for individual policies may be changed from time to time as appropriate. Policies that the Providence Compliance Program administers or has ownership of (*PSJH-CPP policies*) are reviewed on an annual basis.

Note: The Providence-wide policies listed below are posted on the <u>PolicyStat®</u> platform and are available to all members of the workforce organization-wide. For the most up-to-date version of the policy, please refer to the version posted on <u>PolicyStat®</u>.

PROV-FIN-519 Discounts for Health Services PROV-FIN-520 Medicare Bad Debts PROV-FIN-521 Federal Health Program Cost Reports PROV-MED-310 Physician Compensation Review PROV-RIS-728 Research Misconduct **PSJH-CLIN-1203** Nondiscrimination PSJH-CLIN-1206 Patient Rights and Responsibilities PSJH-CLIN-1208 Reportable Quality Events (WA & AK Only) PSJH-CLIN-1212 Event Reporting and Response Policy and Procedure PSJH-CPP-700 Compliance Program PSJH-CPP-711 Fraud, Waste and Abuse Prevention and Detection PSJH-CPP-715 Records Retention and Disposal **PSJH-CPP-718** Vendor/Supplier Interactions PSJH-CPP-719 Gifts, Gratuities and Business Courtesies PSJH-CPP-722 Code of Conduct PSJH-CPP-724 Conflicts of Interest in Research PSJH-CPP-730 Use of Compliance and Related Titles by Employed Caregivers PSJH-CPP-731 Creation of System-Wide Policies PSJH-CPP-732 Anti-Corruption Compliance **PSJH-CPP-733** Non-Retaliation **PSJH-CPP-735** Investigations PSJH-CPP-736 Compliance Hotline PSJH-CPP-737 Reporting and Investigating Potential Compliance Issues and Reportable Compliance Events PSJH-CPP-741 Disclosure Program **PSJH-CPP-743** Compliance Reporting Obligations PSJH-CPP-850 General Privacy PSJH-CPP-850.05 Privacy and Security Glossary PSJH-CPP-850.06 General Uses and Disclosures of Protected Health Information PSJH-CPP-850.07 Rights of Individuals with Respect to Protected Health Information PSJH-CPP-850.08 Notice of Privacy Practices PSJH-CPP-850.09 Administrative Requirements for Protected Health Information PSJH-CPP-850.10 HIPAA–Business Associate Agreement Standard PSJH-CPP-850.14 Protected Health Information Breach Notification Standard PSJH-CPP-850.15 Use and Disclosures of Protected Health Information Disclosures Authorized by Law Standard PSJH-CPP-850.16 Protected Health Oversight Activities Standard PSJH-CPP-850.17 Social Security Number Collection, Use, Disclosure and Management

PSJH-CPP-851 Privacy Sanctions PSJH-EIS-903 Web Accessibility **PSJH-EIS-950** Information Security Management PSJH-EIS-950.01 Security Risk Management Standard PSJH-EIS-950.02 Security Compliance Standard PSJH-EIS-950.03 Security Assessment and Authorization Standard PSJH-EIS-950.04 Vendor Security Risk Management Standard PSJH-EIS-950.06 Security Exception Processing Standard PSJH-EIS-950.07 PCI Compliance Standard PSJH-EIS-950.08 Acceptable Use Standard **PSJH-EIS-953** Access Management PSJH-EIS-953.02 Password Management Standard PSJH-EIS-953.07 Identity Theft Standard PSJH-FIN-524 Advanced Beneficiary Notices PSJH-GOV-208 Conflicts of Interest PSJH-GOV-217 Background Check for System Board of Directors, Community Governance, and Foundation Boards PSJH-GOV-220 Providence Ventures Conflict of Interest PSJH-HIM-1501 Designated Record Set PSJH-MED-305 Responsibility for Medical Staff Appointments and Re-Appointment PSJH-MED-308 Excluded Individual Checks – Medical Staff PSJH-MED-314 Non-Monetary Compensation and Medical Staff Incidental Benefits **PSJH-MISS-100** Charity Care-Financial Assistance PSJH-MISS-103 Community Benefit PSJH-MISS-150 Gift Acceptance PSJH-RCS-1602 Internal Coding Quality Audits **PSJH-RCS-1603** Bad Debt Assignments PSJH-REH-1004 Health Care Industry Representatives-HCIR in Patient Care Areas PSJH-REH-1005 Excluded Individual and Entities Checks – Vendors **PSJH-REH-1006** Supplier Onboarding PSJH-REH-1011 Supplier Diversity, Equity, and Inclusion PSJH-RESO-1408 Disclosures to Law Enforcement **PSJH-RIS-758 Business Continuity Management**

Human Resources

NOTE: Refer to the <u>Caregiver Service Portal</u> for the most up-to-date version of these ministry specific policies.

- Background Check and Excluded Individual Policy.pdf
- <u>Confidentiality Policy.pdf</u>
- <u>Counseling and Corrective Action Policy.pdf</u>
- Harassment Discrimination Retaliation Policy.pdf
- <u>Reasonable Accommodation Policy.pdf</u>
- <u>Release of Caregiver Information Policy.pdf</u>
- Social Media Policy.pdf
- <u>Standards of Conduct Policy.pdf</u>
- Use of Personal Devices Policy.pdf
- Work Incident Reporting and Investigation Policy.pdf

Appendix B: Key Foundational Materials Supporting the Program

Listed below are the foundational materials supporting the Compliance Program in effect as of the approval date of the active Compliance Program Description. Supporting materials may be added, revised, or retired over time. Additionally, naming conventions for these materials may be changed from time to time as appropriate.

- Audit and Compliance Committee Charter
- Audit and Compliance Committee Minutes
- Board General Q4 Minutes
- Board Resolution to Affirm Compliance Program
- <u>Code of Conduct</u>
- Code of Conduct Acknowledgement
- COI Annual Campaign Flyer
- COI Annual Disclosure Form
- COI Annual Launch Information
- COI Gifts-FAQ
- COI Program Overview
- COI Tip Sheet
- COIR Committee Charter
- COIR Process Slide
- COIR Standard Management Plan Template
- Community Mission Board Presentation
- Compliance Education 2022 Compliance, Privacy and Security Education NCO Part 1
- Compliance Education 2022 Compliance, Privacy and Security Education NCO Part 2
- Compliance Education 2023 Qstream Questions Final GE
- Compliance Education 2023 Qstream Questions Final HCC
- Compliance Education 2023 Qstream Questions Final Provider
- <u>Compliance Education Annual Launch Information</u>
- Compliance Education Development Team Charter
- Compliance Education Program Overview
- <u>Compliance Education Webinars</u>
- Compliance Monitoring Program Overview
- <u>Compliance Program Contacts</u>
- Compliance Program Self-Assessment_2024 (based on the HCCA-OIG Guidance)
- Compliance Program Self-Assessment_2024 (based on the DOJ Guidance)
- <u>Compliance Roadmaps</u>
- <u>Compliance Week Information</u>
- <u>Compliance Work Plan</u>
- <u>Compliance Auditing-Monitoring Work Plan</u>
- Division Compliance & Risk Committee (DCRC) Charter Template
- Division Compliance Committee Linkage
- Exclusion Screening Process Employees
- Exclusion Screening Process Global Partners Vendors
- Exclusion Screening Process Medical Staff
- Exclusion Screening Process Vendors
- Exclusion Screening Program Exclusion List Overview

- Exclusion Screening Program Overview
- HIPAA Access to EMR Risk Areas–BTG 3.11
- HIPAA Business Associate Agreement (BAA) Template
- HIPAA Chemical Dependency Business Associate Agreement (BAA) Template
- HIPAA Notice of Privacy Practices English
- HIPAA Privacy and Security What You Need to Know
- Integrated Risk Management (IRM) Framework
- Integrity Hotline FAQ
- Integrity Hotline Online (Link)
- Integrity Hotline Poster Prov OIG
- Integrity Hotline Publication Method Examples
- Investigation Report Template
- Investigations Field Guide
- Investigations Flow Chart
- Investigator HR Triage
- Investigator Training Credibility Determination
- Investigator Training Planning the Investigation
- Investigator Training Report Writing
- Investigator Training Trauma Informed
- Lab Compliance Committee Charter
- M&A Playbook Overview
- Mandatory Provider Training Sub-Committee Charter
- MDaudit Enterprise Overview Brochure
- Ministry Compliance Liaisons (Link)
- Notice of Nondiscrimination and Communication Assistance English
- Org Chart PSJH Legal Structure
- Org Structure Compliance Functions
- PAPOC Charter Final with Goals
- Patient Rights and Responsibilities Poster English
- Pharmacy Compliance and Account Workgroup Charter
- Policy Advisor Committee Charter
- Policy Development & Vetting Process Flowchart
- Policy Management Approval Flowchart
- Policy Management Office Overview
- Privacy Sanctions Presentation
- Protenus Rollout Frequently Asked Questions
- Protenus Rollout Message for Core Leaders and Caregivers
- Providence Record Maintenance, Retention and Destruction Schedule
- PSJH Contract Checklist
- PSJH Council Structure Relationship
- Publication Method Examples for Disciplinary Standards
- Risk Assessment Planning Inputs
- Risk Assessment Process-Work Plan Development
- Supplier Onboarding Process Flow
- System Compliance Committee Charter
- When to Call Compliance Flyer