

Welcome to OMIG Compliance, Managed Care and Self-Disclosure Regulations

 **RIVKIN RADLER** LLP
ATTORNEYS AT LAW

HEALTHCARE COMPLIANCE LUNCH & LEARN SERIES



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Purpose

- Revisions to the NYS Social Service Law 363-d, effective April 1, 2020, were to align the NYS laws with applicable Federal laws. However, regulations were not amended at that time.
- On July 13, 2022, OMIG published proposed regulations to accompany the revised NY Social Services Law with the intention of aligning the regulations with State and Federal laws.
- Proposed changes address the following:
 1. Provider compliance programs
 2. Medicaid managed care fraud, waste, and abuse prevention programs under the Medicaid program
 3. Self-Disclosure Obligations regarding Medicaid overpayments



Provider Compliance Programs

- Applicability: Who must comply?
- “Required providers”:
 1. Any person subject to Articles 28 and 36 of the PHL;
 2. Any person subject to Articles 16 and 31 of the Mental Hygiene Law;
 3. Any *managed care provider* (as defined in NY SSL 364-j) or MLTC (pursuant to PHL 4403-f)(“MMCO”); and
 4. Any other person for whom the MA program is, or is reasonably expected by the person to be, a ***substantial portion of their business.***



Provider Compliance Program

- Dollar threshold has changed for “**substantial portion of business operations**”.
- “Substantial portion of business operations” means:
 - when a person claims or has claimed, or should be reasonably expected to claim, at least \$1 million, in the aggregate, in any consecutive twelve-month period, directly or indirectly, from the MA program; or
 - when a person receives or has received, or should be reasonably expected to receive, at least \$1 million, in the aggregate, in any consecutive twelve-month period, directly or indirectly, from the MA program.
- Reminder: In calculating whether you meet the threshold, claims should include both straight Medicaid claims and managed Medicaid claims.



Affected Individuals

- Throughout the regulations there is reference to “Affected Individuals” of the provider with respect to particular requirements, such as training and education.
- “Affected Individuals” means all persons who are affected by the required provider’s risk areas including the required provider’s employees, the chief executive and other senior administrators, managers, contractors, agents, subcontractors, independent contractors, and governing body and corporate offices.



Independent Contractors

- Required Providers must ensure that their contracts with contractors, agents, subcontractors, and independent contractors (“ICs”)
 1. Specify that the IC’s are subject to the required provider’s compliance program, to the extent the ICs are “Affected Individuals”.
 2. Include termination provisions for failure to adhere to the required provider’s compliance program requirements.
- Training and education
- Exclusion checks



Effective Compliance Program

- As a condition of receiving payment under the MA Program, required providers must adopt, implement, and maintain an **effective compliance program**.
- “Effective Compliance Program” is defined as a compliance program adopted and implemented by the required provider that, at a minimum, satisfies the requirements of Part 521 and is designed to be compatible with the provider’s characteristics, which means that it:
 - Is well-integrated into the company’s operations and supported by the highest levels of the organization, including the chief executive, senior management, and the governing body;
 - Promotes adherence to the required provider’s legal and ethical obligations; and
 - Is reasonably designed and implemented to prevent, detect, and correct non-compliance with MA program requirements, including fraud, waste, and abuse most likely to occur for the required provider’s risk areas and organizational experience.



1- Written Policies and Procedures

- Similar to current regs, the proposed regs require providers to have written policies, procedures, and standards of conduct, and they outline certain topics that must be addressed in the policies.
- Policies must be “available, accessible, and applicable to all affected individuals”.
 - There is emphasis in the new regulations on accessibility.
- Disciplinary standards must be included in the policies which establish “the degrees of disciplinary actions the required provider **must** take, with intentional or reckless behavior being subject to more significant sanctions. Sanctions may include oral or written warnings, suspension, and/or termination. The policies must conform with collective bargaining agreements when applicable.
- Also, policies must comply with DRA requirements (42 USC 1396(a)(68)) regardless if the required provider does not meet the \$5 million DRA threshold.



2- Compliance Officer

- The Compliance Officer (“CO”) is responsible for carrying out day-to-day activities of the compliance program. The CO is to report directly and be accountable to chief executive or another senior manager.
- CO responsibilities must be the CO’s sole duties, or, depending on the size, complexity, resources, and culture of the required provider and the complexity of the tasks, the CO may be assigned other duties provided that such other duties do not hinder the CO in carrying out their primary responsibilities under Part 521.
 - List of ‘primary responsibilities’ are included in the regs.
- Provider must ensure the CO is allocated **sufficient staff and resources to satisfactorily perform their responsibilities** for the day-to-day operation of the compliance program based on the required provider’s risk areas and organizational experience.
- The CO and appropriate compliance personnel must have access to all records, documents, information, facilities, and affected individuals related to carrying out their responsibilities.



3- Compliance Committee

- Required provider to designate a Compliance Committee (“CC”) responsible for coordinating with the CO to ensure it is conducting business in an ethical and responsible manner consistent with its compliance program.
- CC Charter required which outlines duties and responsibilities, membership, designation of chair, and frequency of meetings.
- CC responsible to ensuring CO is allocated sufficient funding, resources, and staff to fully perform their responsibilities.
- Membership at a minimum comprised of senior managers. CC to meet at least quarterly, and annually shall review and update the CC Charter.
- CC reports to chief executive and governing body.



4- Training and Education

- As currently required, providers must establish and implement a training and education program for the CO and all affected individuals. Done annually and promptly upon hiring as part of orientation.
- Training and education to be in a form and format accessible and understandable to all affected individuals, consistent with Federal and State language and other access laws, rules, or policies.
- Certain topics are included in the regs which must be addressed in the training and education, including the provider's risk areas and organizational experience.
- For Medicaid Managed Care Organizations (MMCOs) only, training and education should include info re: the fraud, waste, and abuse prevention program, and any applicable terms of the MMCO's contract with the DOH to participate as an MMCO.
- Must develop a training plan which, at a minimum, outlines the subjects/topics, timing, and frequency; which affected individuals are required to attend; how attendance is tracked; and how the effectiveness will be periodically evaluated.



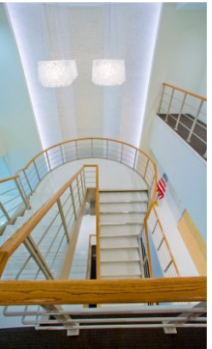
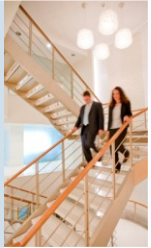
5- Lines of Communication

- Similar to current requirements, providers must establish and implement effective lines of communication which ensure confidentiality for the provider's affected individuals.
- Lines of communication must be accessible to all affected individuals and allow for questions to be asked regarding compliance issues and allow for issues to be reported.
- Must ensure that the confidentiality of persons reporting compliance issues is maintained *unless* the matter is subject to disciplinary proceeding, referred to, or under investigation by, MFCU, OMIG, or law enforcement, or disclosure is required during legal proceeding. Such persons must be protected under policy for non-intimidation and non-retaliation.



6- Disciplinary Standards

- Policies and procedures re: disciplinary standards and enforcement must be published and disseminated to all affected individuals and be incorporated into provider training plan.
- Required provider must enforce its disciplinary standards ***fairly and consistently***, and the same disciplinary action should apply to all levels of personnel.





7- Auditing and Monitoring

- Must perform ongoing audits by internal auditors, or external auditors as appropriate, who have expertise in state and federal MA program requirements and applicable laws or have expertise in the subject area of the audit.
 - Audits by State or Fed government entities are not considered external audits.
- As a result of audits, identified overpayments must be reported, returned, and explained (Part 521-3) and prompt corrective action taken to prevent recurrence.
- Must conduct Compliance Program Review at least annually.
 - May be carried out by CO, CC, external auditors, or other staff designated by the provider, provided they have necessary knowledge and expertise.
 - Reviews should include on-site visits, interviews with affected individuals, review of records, surveys, or any other comparable method the required provider deems appropriate, provided the method does not compromise the independence or integrity of the review.
 - Implementation and results must be documented and shared with chief executive, senior management, CC, and the governing body.
- Exclusion checks must be conducted at least every 30 days.
- Required providers must require ICs to comply with the exclusion check requirements, and MMCOs must require their participating providers and subcontractors to comply, as applicable.



8- Responding to Compliance Issues

- Must establish and implement procedures and systems for promptly responding to compliance issues, promptly investigating and correcting problems to reduce potential for recurrence and ensure ongoing compliance.
- Must document the investigation including alleged violations, the description of investigation process, copies of interview notes and other documents essential for demonstrating that the required provider completed a thorough investigation. Where appropriate, the required provider may retain outside experts, auditors, or counsel to assist with the investigation.
- Must document the disciplinary action and corrective action implemented.
- If provider identifies credible evidence or credibly believes that a State or Federal law, rule, or regulation has been violated, the required provider must promptly report the violation to the appropriate government entity. CO shall receive copies of any such reports.



Certification

- Required Providers must certify upon enrollment and annually, in a form and manner required by OMIG and DOH, that the required provider has met SSL 363-d and Part 521 requirements.
- Participating providers (provider of medical care/services that has a provider agreement with an MMCO) who are also required providers must provide a copy of the certification upon signing a provider agreement with the MMCO and annually thereafter.
 - MMCO must maintain a method for submitting certification on MMCO's website.



Compliance Program Review

- OMIG can, at any time, review a provider to determine if they adopted, implemented, and maintained an effective compliance program.
- OMIG will provide written notification of the review period and procedures for completing the review. Notice will be sent to correspondence or pay-to address on file with DOH or last known address.
- Provider must respond in the manner proscribed by OMIG (including requested records) within 30 days of date on OMIG's notice. For good cause shown, OMIG may extend the 30-day period to respond.
- Notwithstanding compliance program review, OMIG may separately review an MMCO's compliance program as part of Medicaid program integrity review. (SSL 364-j)
- After completing review, notice will be provided of results which:
 1. Advises provider if program satisfactorily met Part 521 requirements
 2. Advises provider of recommendations for improving the program or correct deficiencies
 3. If not satisfactorily met, OMIG will advise (in addition to other action authorized by law), that they may be subject to monetary penalties (Part 516), and participation in Medicaid may be revoked (Part 504)



Medicaid Managed Care Fraud, Waste, and Abuse Prevention

- Part 521-2 added to require MMCOs to adopt and implement programs designed to detect and prevent fraud, waste, and abuse in the MA program.
- This part applies to MMCOs.
- 10 NYCRR 98-1.21 and 11 NYCRR 86.6 sets forth requirements for the establishment and operation for certain managed care plans, of fraud and abuse prevention plans and programs. MMCOs subject to those sections must continue to comply with those requirements, provided that, as it pertains to MMCOs' participation in the MA program, the requirements of Part 521 are met.



Medicaid Managed Care Fraud, Waste, and Abuse Prevention

- “Abuse” means practices that are inconsistent with sound fiscal, business, medical, or professional practices, and which result in unnecessary costs to the Medicaid program, payments for services that were not medically necessary, or payments for services which fail to meet recognized standards for health care. It also includes enrollee practices that result in unnecessary costs to the Medicaid program.
- “Fraud” means an intentional deception or misrepresentation made with the knowledge that the deception could result in some unauthorized benefit to the provider, Contractor, Subcontractor, or another person and includes the acts prohibited by section 366-b of the Social Services Law. It also includes any other act that constitutes fraud under applicable Federal or State law.



Medicaid Managed Care Fraud, Waste and Abuse Prevention

- MMCO and its subcontractors must retain records as required in contract with DOH and required by regs and must cooperate with OMIG, DOH, and MFCU requests for information and allow access to their facilities at any time. Copies must be provided free of charge.
- MMCO and its subcontractors must permit OMIG, DOH, and MFCU to conduct private interviews of MMCO personnel, its subcontractors, and their personnel, witnesses, and enrollees. MMCO personnel and subcontractors must cooperate fully in making personnel available in person for interviews, consultation, grand jury proceedings, pre-trial conferences, hearings, trial and other processes, including investigation, at MMCO and subcontractor's own expense.



MMCO and Independent Contractors

- MMCO must adopt, implement, and maintain a compliance program that satisfies Part 521-1 and incorporates policies and procedures for preventing, detecting, and investigating fraudulent, wasteful, or abusive activities by its participating providers, non-participating providers, Ics, and any other person the MMCO or its subcontractors pay for ordering, providing, furnishing, or arranging for a service to an MA program recipient.
- MMCO must ensure that contracts with ICs and participating providers specify that the ICs and participating providers are subject to audit, investigation, or review under the MMCO's fraud, waste, and abuse prevention program, to the extent the IC or participating provider relate to the MMCO's participation in the MA program.



MMCO Compliance Program Requirements

- MMCO must require its CO to be responsible, except where noted, for implementing the requirements of Part 521-2 and to coordinate with the MMCO's SIU director, where applicable.
- MMCO must include, as part of its training, the training of all personnel involved in identifying and evaluating instances of potential fraud, waste, and abuse.
- MMCO must conduct audits, investigations, and reviews of at least 1% or more of the aggregate of MA program claims it pays to providers and subcontractors, based on the prior year's total claims paid by the MMCO -- all consistent with lookback periods in MMCO's contract with DOH to participate.



Special Investigations Unit (SIU)

- MMCO must establish an SIU (Special Investigations Unit).
- SIU investigators must be qualified by education or experience (minimum years and prior experience outlined in regs).
- SIU must prepare a work plan at least annually outlining activities for the coming year.
- SIU may delegate all or part of its functions, provided it is not a defense to enforcement that a subcontractor failed to provide effective service enabling the MMCO to comply.
- All delegated subcontractors must comply with relevant regs and must cooperate fully with OMIG and provide assistance required by OMIG, DOH, MFCU, and other law enforcement agencies in the investigation and prosecution of fraud, waste, and abuse.
- MMCO must review its contract for SIU functions to determine if it delegates any management authority. Can't enter into agreement delegating management authority unless it otherwise complies with DOH requirements (10 NYCRR 98-1.11 and 1.18).
 - If delegates management functions, must submit to OMIG and DOH.



Special Investigations Unit (SIU)

- If MMCO has 1,000+ enrollees in the aggregate in any given year, the MMCO must establish a **full time** SIU to identify risk and detect and investigate cases of potential fraud, waste, and abuse, report to OMIG, and electively report fraud to MFCU.
- SIU must be separate and distinct from any other unit or function of MMCO.
- MMCO must dedicate sufficient staff and resources to SIU:
 - Employ at least 1 full-time lead investigator and 1 SIU director based in NYS
 - Employ 1 full-time investigator per 60,000 enrollees (except MLTCP - 1 for 6,000 enrollees)
 - Dedicate an investigator to service a particular county if, on its own, the county meets designated investor-to-enrollee ratio.
 - Also employ or utilize existing employees who are certified coders, clinicians, data analysts, or pharmacists to support work of SIU.



Reporting

- MMCO and its subcontractors must report potential fraud, waste, and abuse to OMIG and potential fraud to MFCU. Reports must be signed by executive officer of MMCO responsible for SIU operations.
- Specific detailed information must be included in the report, which is outlined in the regs.
- MMCO and its subcontractors must immediately refer reasonably suspected criminal activity to OMIG and MFCU in accordance with MMCO's contract with DOH to participate as MMCO.





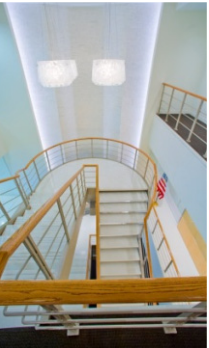
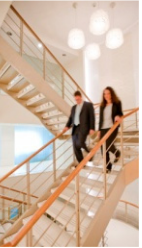
Report, Return, Explain

- MMCO must establish policies and procedures for its participating providers and other subcontractors to report, return, and explain overpayments to MMCO within 60 days of identification.
- MMCO must promptly report all recoveries, including those resulting from provider or subcontractor reporting, returning and explaining an overpayment in (1) its cost reports to DOH, and (2) a monthly report to OMIG in a form and format to be determined by OMIG, or as otherwise specified in the contract to participate as MMCO.
- MMCO to develop fraud, waste, and abuse detection procedures manual.



Fraud, Waste, and Abuse

- MMCO must develop a fraud, waste, and abuse public awareness program focused on cost and frequency of MA program fraud and method to prevent it. MMCO must make info available on its website.
- MMCO must make available on its website info on how and where to report, return, and explain overpayments to MMCO.





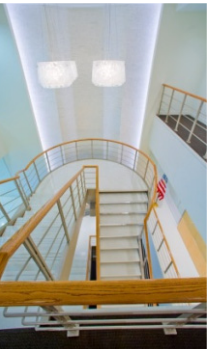
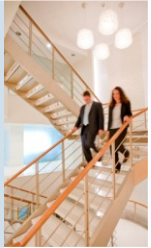
Fraud, Waste, and Abuse Prevention Plan

- Within 90 calendar days of effective date of law, or of signing a new contract with DOH to participate as an MMCO, the MMCO must develop a fraud, waste, and abuse prevention plan and **submit such plan to OMIG**.
- The plan must include:
 - Description of the organization of the SIU
 - If investigators investigating more than 1 state, plan must apportion that % of effort to be devoted to NYS
 - Rationale for staffing levels (if different than requirement)
 - Description of roles, responsibilities, and interactions between the MMCO's CO, SIU, and claims, quality, member services, UR, compliant procedures and underwriting, SIU and MMCO's legal department and SIU and OMIG, DOH, MFCU, and law enforcement
 - Policies and procedures
 - Criteria for internal referral to SIU and reporting to OMIG and DOH
 - Description of controls to prevent and detect potential FWA, including any automated pre-payment claim edits and post-payment claim review
 - Description of training requirements
 - Timetable for implementation of plan, provided it does not exceed 180 calendar days from date MMCO executes contract with DOH to participate.



Fraud, Waste, and Abuse Prevention Plan

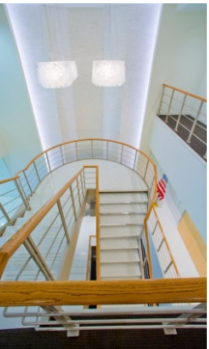
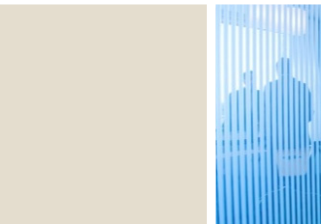
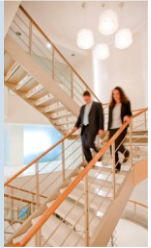
- MMCO must, by due date set by OMIG (no sooner than Jan. 31st of each calendar year), file with OMIG an annual report for preceding calendar year demonstrating satisfaction of requirements.





Self-Disclosure Program

- NYS Social Service Law 363-d(6) requires persons who have received an overpayment to report, return, and explain the overpayment by making a disclosure to OMIG*.
- Applies to payments received directly or indirectly.





Self-Disclosure Program

Overpayments from MMCO:

For overpayments made by an MMCO under the MA program: A person who reports, returns, and explains an overpayment to an MMCO, in accordance with the provisions of 18 NYCRR 521-2.4(f) shall be considered to have satisfied the requirements of subdivision 6 of section 363-d of the Social Services Law, provided that the overpayment is reported and returned to the MMCO by the deadline.



Self-Disclosure Program - Eligibility

A person is eligible to participate in the SDP if:

- (i) the person is not currently under audit, investigation, or review by OMIG that relates to the overpayment;
- (ii) the person is disclosing an overpayment that OMIG has not identified at the time of the disclosure;
- (iii) the overpayment and related conduct are reported by the deadline specified in 521-3.3(b)(1); and
- (iv) the person is not currently the subject of any criminal investigation related to the MA program being conducted by the MFCU or an agency of the US Gov't. or any political subdivision thereof.



Self-Disclosure Program

Be Advised - Regardless of eligibility -

If a person has determined that they have received an overpayment pursuant to section 521-3.3, the person shall submit a Self-Disclosure Statement.



Self-Disclosure Program

Self-Disclosure Statement must include both:

- (i) an estimate of the amount of the overpayment and
- (ii) a detailed explanation of the reason the person received the overpayment, including:
 - (a) a description and explanation of the circumstances that gave rise to the overpayment;
 - (b) how the circumstances were discovered;
 - (c) the date the overpayment was identified;
 - (d) how the amount of the overpayment was calculated;
 - (e) the date(s) the overpayment(s) were received; and
 - (f) the action taken to correct the error which caused the overpayment.



Self-Disclosure Program

- (iii) the person's contact information;
- (iv) data file, in the form and format specified by OMIG;
- (v) whether the person is requesting to repay through installment payments;
- (vi) whether the person is requesting the waiver of any applicable interest;
- (vii) the person's agreement to return the full amount of the overpayment and interest if applicable, as determined by OMIG; and
- (viii) any other data, documentation, or information OMIG shall require through the issuance of guidance or in response to its review of the submission.



Self-Disclosure Program

Deadlines for Reporting:

- (i) the date which is sixty (60) days after the date on which the overpayment was identified; or
- (ii) the date any corresponding cost report is due, if applicable.

- a person has identified an overpayment when that person has or should have, through the *exercise of reasonable diligence*, determined that they have received an overpayment and **quantified the amount of the overpayment.**



Self-Disclosure Program Process

- Submission within 60 days
 - OMIG preliminary review (20 days)
 - Notice of Acceptance/Return
 - Possible Additional Requests (15 days to respond)
 - Self-Disclosure and Compliance Agreement (minimum of 15 days to sign and return)
 - Repayment within 15 days (unless installments approved)
- ❖ Failure to meet timelines = termination in SDP



Self-Disclosure Program: Potential Benefits

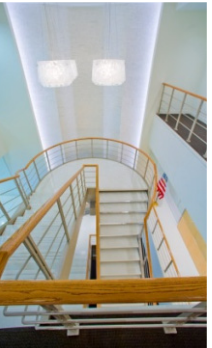
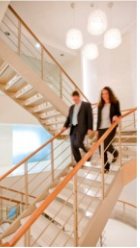
- (i) waive the imposition of interest, in whole or in part;
- (ii) permit repayment through installments;
- (iii) consider the self-disclosure as a mitigating factor in the determination of an administrative enforcement action; and
- (iv) consider the self-disclosure as a factor in determining whether the person has adopted and implemented an effective compliance program.



Self-Disclosure Program

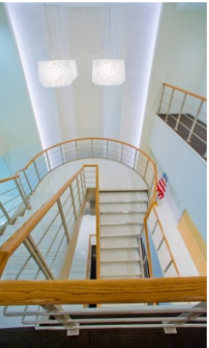
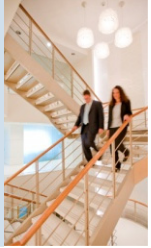
Enforcement

- (a) A person who fails to report, return, and explain an overpayment by the deadline specified in subdivision (b) of section 521-3.3 of this Subpart may be subject to monetary penalties pursuant to section 145-b(4) of the Social Services Law and Part 516 of this Title, and any other sanction or penalty authorized by law.





Self-Disclosure Program





Self-Disclosure Program

- Things to consider:
 - No *de minimus* exceptions
 - Question whether you can void/adjust payments
 - How to handle multiple parties involved
 - No mention on how to calculate overpayment
 - No vehicle for placeholder
 - Expect additional guidance (forms) from OMIG



What's Next:

Comment Period

- Stakeholders may submit comments during comment period through September 12, 2022.
- Comments can be addressed to the Agency Contact

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What's Next:

- OMIG Review
- Final Regulations
- Implementation
 - Subparts 521-1 (Compliance) and 521-2 (MMC) take effect on publication, but enforcement is stayed for 90 days.
 - Subpart 521-3 (Self-Disclosure) takes effect on Notice of Adoption.



What's Next:

Bob's thoughts (**NOT** legal advice):

- Get started!
 - Conduct an Assessment
 - Dive in!
 - ✓ Policies and Procedures
 - ✓ Structure and Resources
 - ✓ Compliance Committee
 - ✓ Training
 - ✓ Risk Assessment
 - ✓ Work Plan



Questions?

Thank you!



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Memberships and Activities

- Former Chair – NYS Bar Association Health Law Section
- HCCA – Past Board Member, Certified in Compliance (CHC)
- Frequent speaker / author on compliance-related topics

Experience

- First Deputy - NYS OMIG
- Interim Compliance/Privacy Officer–Yale New Haven Health
- Compliance Officer – Northeast Health

Focus areas

- Compliance program assessment and assistance
- Internal investigations
- OIG / CMS / OMIG / MFCU / NYS Justice Center - audit/ investigation/exclusion defense, negotiation, and settlements
- Self-disclosures
- Board of Directors, senior management and staff training