

MEDICAL QUALITY ASSURANCE MONTHLY RESULTS REPORT

PROJECT DETAILS

Name	Alameda County Sheriff Office – Medical Operations Consulting: Medical Quality Assurance Review		
Sponsor	Lieutenant Joseph Atienza, Contracts Lieutenant	Project Manager	Tami Bond
Project Summary	To provide Medical Quality Assurance (QA) services for the Alameda County Sheriff Office (ACSO) through the performance of Medical QA reviews to evaluate timeliness of care, appropriateness of assessment, treatment, type of Provider, and level of care. Additionally, to provide Medical QA recommendations to ACSO leadership.		
Methodology	To provide Medical QA reviews for the reporting period, Forvis Mazars performed a medical record review of 15 incarcerated individual (patient) files to determine compliance with applicable requirements and community standards for appropriate access, timeliness, and continuity of care delivery for specified high-risk populations. A compliance score of less than 90-95% warrants a Corrective Action Plan (CAP). Areas at risk for non-compliance are also identified. <i>(See Appendix for Additional Methodology details)</i>		
Report Date	9/20/2024, 10/2/2024	Reporting Period	6/1 – 6/30/2024

ACTIVITIES PERFORMED BY PROJECT TEAM

- Submitted Grievance Continuous Quality Improvement final report.
- Attended weekly scheduled Multi-Disciplinary meetings.
- Received and reviewed reports for the reporting period.
- Conducted applicable monthly medical record QA and Continuous Quality Improvement (CQI) reviews.

PROJECT SCHEDULE

- Upcoming On-site Clinical Observation Dates:
 - 9/25 – 9/26/2024 (Dr. Lee; Faith Saporantos, RN; Patricia Wong, RN; Tami Bond)

COMMENDATIONS

- Wellpath June 2024 MAC meeting held on 8/27/2024 with no commendations or key accomplishments identified.

SUMMARY

For the reporting period of 6/1 – 6/30/2024, Forvis Mazars Medical QA review identified opportunities for improvement (Observations) for the Clinical Team (Wellpath) to assure the delivery of quality care focusing on the following areas, in accordance with applicable National Commission on Correctional Health Care (NCCHC) standards: Governance and Administration, Patient Care and Treatment, Special Needs and Services, Medical: Legal Issues.

Onsite Clinical Observations are also provided in this report and include opportunities to improve compliance with quality assurance standards, medical and applicable policies, and/or applicable regulations. Areas at risk for non-compliance, including collaborative management and information sharing across different teams and systems, and adequacy of clinical staffing are also identified.

Forvis Mazars shall issue a formal Correction Action Plan (CAP) every quarter informed by the ongoing identified areas of noncompliance within the monthly reviews.

Demonstrated Areas of Improvement	
Compliance rate of greater than 90-95%.	Increase in compliance rate of 20% or greater.
NA	9. Restraint, Seclusion & Segregated Inmates.

Areas of Risk	
Compliance rate of 0%.	1. Access to Care. 10. Informed Consent & Right to Refuse.
Compliance rate of less than 90%.	Decrease in compliance rates of 20% or greater.
1. Access to Care. 2. Grievance Process for Health Care Complaints. 3. Receiving Screening. 4. Initial Health Assessment. 5. Nonemergency Health Care Requests & Services. 6. Continuity, Coordination, and Quality of Care. 7. Discharge Planning. 8. Patients With Chronic Disease & Other Special Needs. 9. Restraint, Seclusion & Segregated Inmates. 10. Informed Consent & Right to Refuse.	2. Grievance Process for Health Care Complaints. 6. Continuity, Coordination, and Quality of Care. 7. Discharge Planning. 8. Patients With Chronic Disease & Other Special Needs.
Identified areas at risk for non-compliance which require collaborative management and information sharing across different teams and systems.	Identified areas at risk for non-compliance which require clinical staffing management to ensure prescriber and nursing time adequate to meet patient care delivery needs.
1. Access to Care. 2. Grievance Process for Health Care Complaints. 3. Receiving Screening. 5. Nonemergency Health Care Requests & Services. 6. Continuity, Coordination & Quality of Care. 7. Discharge Planning. 8. Patients With Chronic Disease & Other Special Needs. 9. Restraint, Seclusion & Segregated Inmates. 10. Informed Consent & Right to Refuse.	3. Receiving Screening. 4. Initial Health Assessment. 5. Nonemergency Health Care Requests & Services. 6. Continuity, Coordination & Quality of Care. 7. Discharge Planning. 8. Patients With Chronic Disease & Other Special Needs. 9. Restraint, Seclusion & Segregated Inmates. 10. Informed Consent & Right to Refuse.

MEDICAL QUALITY ASSURANCE MONTHLY RESULTS REPORT

MEDICAL RECORD REVIEW: RESULTS

NCCHC Standard (E) = Essential (I) = Important	Prior Month	Current Month			
	Percentage Compliant goal 90-95%*	Files Compliant	Applicable Files Reviewed	Percentage Compliant goal 90-95%*	Details for Non-Compliant Files

* The compliance threshold goal for QA review is consistent with the compliance threshold for the related CQI studies. See Appendix for details.

I. Section A – Governance and Administration

1. Access to Care A-01 (E)	6.7% (1/15)	0	15	0.0% (0/15)	15 of 15 files non-compliant: <u>Patient 1:</u> "Hemodialysis," "Hypertension," "Diabetes Mellitus Type 2," "Bilateral Below Knee Amputation," "History of Deep Vein Thrombosis," "Vision Impaired/Blind Right Eye (reported Glaucoma)," "Hyperlipidemia," "Gastroesophageal Reflux Disease," "Self-Harm Behavior/Self-Injury," "Lower Level/Lower Bunk Restriction – Mobility Impairment: Right Prosthetic only, missing Left/Wheelchair/Walker/Crutches." <u>Patient 2:</u> "COVID-19," "Failure to Thrive," "Essential Tremors," "Pre-Diabetes," "Venous Stasis Ulcers," "Developmental Disability," "Medical Isolation – COVID-19," "ADA/Special Needs & Lower Level/Lower Bunk Restriction – Mobility Impairment: Wheelchair bound," "Other: Weekly Unna Boot," "Diversion – Palming/Cheeking/Hoarding Pills." <u>Patient 3:</u> "Bipolar Disorder," "Schizophrenia," "Depression," "Anxiety," "Feigning Illness," "Adjustment Reaction," "Self-Harm Behavior/Self-Injury," "Suicide Watch." <u>Patient 4:</u> "Lice," "Medical Isolation – Positive PPD, Lice." <u>Patient 5:</u> None listed. "Unspecified Schizophrenia Spectrum and Other Psychotic Disorder," "Amphetamine Induced Disorder." <u>Patient 6:</u> "Hyperthyroidism," "Obesity," "Vitamin D Deficiency," "Seborrheic Dermatitis," "Hyperprolactinemia," "Constipation," "Lice," "Schizophrenia," "Psychotic Disorder," "Medical Isolation – Lice." <u>Patient 7:</u> "Trichomoniasis," "Anxiety," "Post-Traumatic Stress Disorder," "Bipolar Disorder," "Depression," "Self-inflicted wounds – Left Forearm, Right Neck," "Self-Harm Behavior/Self-Injury," "Suicide Watch," <u>Patient 8:</u> None listed. "Self-Harm Behavior/Self-Injury," "Post-Traumatic Stress Disorder," "Depression," "Anxiety," "Impulse Control Disorder," "Attention Deficit Hyperactivity Disorder," "Suicide Watch." <u>Patient 9:</u> "Diversion – Palming/Cheeking/Hoarding Pills." <u>Patient 10:</u> "Obesity," "Chronic Multiple Joint Pain," "Thrombocythemia," "Right Sciatica," "Polycythemia," "Chronic Periodontitis," "Bipolar Disorder," "Schizophrenia," "Lower Level/Lower Bunk Restriction – Mobility Impairment."
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MEDICAL RECORD REVIEW: RESULTS

NCCHC Standard (E) = Essential (I) = Important	Prior Month	Current Month			
	Percentage Compliant <i>goal 90-95%*</i>	Files Compliant	Applicable Files Reviewed	Percentage Compliant <i>goal 90-95%*</i>	Details for Non-Compliant Files
					<p><u>Patient 11:</u> "Bipolar Disorder," "Anxiety," "Depression," "Schizophrenia." <u>Patient 12:</u> "Lice," "Medical Isolation – Lice, PPD refusal/failed screening," <u>Patient 13:</u> "Pregnant," "History Preeclampsia," "Acute Cystitis," "Self-Harm Behavior/Self-Injury," "Bipolar Disorder," "Schizophrenia," "Anxiety," "Depression," "Lower Level/Lower Bunk Restriction – Pregnancy." <u>Patient 14:</u> None listed. "Chronic Low Back Pain," "Bacterial Vaginosis," "Migraine Headache." <u>Patient 15:</u> None listed. "Gravely Disabled," "Psychotic Disorder." Risk for non-compliance: *Requires collaborative management and information sharing across different teams and systems.</p>
2. Grievance Process for Health Care Complaints A-10 (I)	100.0% (3/3)	1	2	50.0% (1/2)	<p>1 of 2 files non-compliant: <u>Patient 10:</u> Inconsistent documentation to support delayed grievance notification to medical, linkage to patient sick call refusals, medical response, and mental health coordination. Risk for non-compliance: *Requires collaborative management and information sharing across different teams and systems (i.e., Inmate Grievance Form).</p>
II. Section E – Patient Care and Treatment					
3. Receiving Screening E-02 (E)	53.3% (8/15)	7	15	46.7% (7/15)	<p>8 of 15 files non-compliant: <u>Patients 1, 2, 3, 5, 7, 9, 14, 15:</u> Receiving Screening/Abbreviated Receiving Screening not started timely. Completed beyond 8-hours from applicable Book-In time. Risk for non-compliance: *Requires collaborative management and information sharing across different teams and systems. *Requires clinical staffing management to ensure nursing time adequate to meet patient care delivery needs.</p>
4. Initial Health Assessment E-04 (E)	15.4% (2/13)	3	12	25.0% (3/12)	<p>9 of 12 files non-compliant: <u>Patients 2, 6, 9, 11, 12:</u> No evidence of IHA. "Not Started" with no evidence or untimely scanning of related patient refusal. <u>Patients 1, 3, 7, 10:</u> IHA performed beyond the required 14-calendar days of the patient's Book-In. Risk for non-compliance: *Requires clinical staffing management to ensure prescriber and nursing time is adequate to meet patient care delivery needs.</p>

MEDICAL RECORD REVIEW: RESULTS

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	Percentage Compliant <i>goal 90-95%*</i>	Files Compliant	Applicable Files Reviewed	Percentage Compliant <i>goal 90-95%*</i>	Details for Non-Compliant Files
5. Nonemergency Health Care Requests & Services E-07 (E)	28.6% (2/7)	1	8	12.5% (1/8)	7 of 8 patients with Sick Call Requests > or = 50% with "Nursing Assessment(s)" performed beyond the required 24-hours from initial receipt. Review was limited to patient Sick Call Requests of 100 for each patient, as applicable. <u>Patient 1:</u> (1 of 1) Nursing Assessments performed beyond 24-hours from initial receipt of patient Sick Call Request. <u>Patient 6:</u> (3 of 5) Nursing Assessments performed beyond 24-hours from initial receipt of patient Sick Call Request. <u>Patient 7:</u> (3 of 5) Nursing Assessments performed beyond 24-hours from initial receipt of patient Sick Call Request. <u>Patient 9:</u> (7 of 8) Nursing Assessments performed beyond 24-hours from initial receipt of patient Sick Call Request. <u>Patient 10:</u> (22 of 35) Nursing Assessments performed beyond 24-hours from initial receipt of patient Sick Call Request. <u>Patient 11:</u> (4 of 4) Nursing Assessments performed beyond 24-hours from initial receipt of patient Sick Call Request. <u>Patient 14:</u> (10 of 12) Nursing Assessments performed beyond 24-hours from initial receipt of patient Sick Call Request. <u>Risk for non-compliance:</u> *Requires collaborative management and information sharing across different teams and systems. *Requires clinical staffing management to ensure prescriber and nursing time is adequate to meet patient care delivery needs.
6. Continuity, Coordination, & Quality of Care E-09 (E)	86.7% (13/15)	10	15	66.7% (10/15)	5 of 15 files non-compliant: <u>Patient 1:</u> Incomplete patient assessments status post unwitnessed patient fall – no evidence of documented vital signs immediately after the reported fall, and inconsistent follow-up monitoring. No evidence Ortho and Physical Therapy task(s) for Bilateral Below Knee Amputation, missing prosthetic. No referrals selected in ITR Receiving Screening (i.e., Medical, Mental Health, Chronic Care, Dental, Discharge Planner). <u>Patient 3:</u> "Dental" incomplete. No task created for 8/10 tooth pain complaints. <u>Patient 4:</u> No evidence of Return from Off-Site Care Visit assessment for continuity and care coordination upon return from one of the multiple inpatient hospitalizations. Inconsistent medication management – no medications ordered for chronic mental health condition for consecutive months without supporting rationale.

MEDICAL RECORD REVIEW: RESULTS

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	Percentage Compliant goal 90-95%*	Files Compliant	Applicable Files Reviewed	Percentage Compliant goal 90-95%*	Details for Non-Compliant Files
					<p><u>Patient 7</u>: No evidence of Return from Off-Site Care Visit assessment for continuity and care coordination upon return from one of the multiple inpatient hospitalizations.</p> <p><u>Patient 15</u>: Inconsistent medication management – no medications ordered for chronic mental health condition for consecutive months without supporting rationale.</p> <p><u>Risk for non-compliance</u>:</p> <p><u>Patient 2</u>: Inconsistent documentation for ordered Wound Care.</p> <p><u>Patient 8</u>: Incomplete Emergency Response Scribe Sheet.</p> <p><u>Patients 4, 7, 15</u>: Incomplete Return from Off-Site Care Visit documentation for continuity and care coordination.</p> <p><u>Patients 1, 2, 4, 5, 8, 9, 10, 12, 13, 15</u>: Multiple “Mental Health” referrals with no medical record visibility of consultation completion and related outcome.</p> <p>*Requires collaborative management and information sharing across different teams and systems.</p> <p>*Requires clinical staffing management to ensure prescriber and nursing time is adequate to meet patient care delivery needs.</p>
7. Discharge Planning E-10 (E)	92.3% (12/13)	3	7	42.9% (3/7)	<p>4 of 7 files non-compliant:</p> <p><u>Patients 4, 5, 8, 13</u>: No “Discharge Planner” task created. Patient requires DP consult. Incomplete prior to release.</p> <p><u>Risk for non-compliance</u>:</p> <p><u>Patients 6, 10, 12, 14, 15</u>: No “Discharge Planner” task created. Patient requires DP consult. Currently still in-custody.</p> <p>*Requires collaborative management and information sharing across different teams and systems.</p> <p>*Requires clinical staffing management to ensure prescriber and nursing time is adequate to meet patient care delivery needs.</p>
III. Section F – Special Needs and Services					
8. Patients With Chronic Disease & Other Special Needs F-01 (E)	66.7% (4/6)	1	5	20.0% (1/5)	<p>4 of 5 files non-compliant:</p> <p><u>Patient 1</u>: No “Chronic Care” tasks created for End Stage Renal Disease on Hemodialysis, Hypertension, Diabetes Mellitus.</p> <p><u>Patient 2</u>: Inconsistent “Chronic Care” follow-up post inpatient hospitalizations.</p> <p><u>Patient 10</u>: Inconsistent “Chronic Care” follow-up for recent Thrombocytopenia diagnosis, Hepatitis A work-up.</p> <p><u>Patient 14</u>: No “Chronic Care” tasks created for chronic back pain.</p> <p><u>Risk for non-compliance</u>:</p>

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	Percentage Compliant <i>goal 90-95%*</i>	Files Compliant	Applicable Files Reviewed	Percentage Compliant <i>goal 90-95%*</i>	Details for Non-Compliant Files
					<p>*Requires collaborative management and information sharing across different teams and systems.</p> <p>*Requires clinical staffing management to ensure prescriber and nursing time is adequate to meet patient care delivery needs.</p>
IV. Section G – Medical: Legal Issues					
9. Restraint, Seclusion & Segregated Inmates G-01 & G-02 (E)	0.0% (0/2)	1	4	25.0% (1/4)	<p>3 of 4 file non-compliant: <u>Patients 3, 7, 8:</u> Inconsistent or missing evidence of patient monitoring for Suicide Attempt(s). <u>Risk for non-compliance:</u> <u>Patients 1, 13:</u> Inconsistent supporting documentation to close monitoring. <u>Patient 9:</u> Inconsistent supporting documentation to explain absence of close monitoring action when deemed appropriate (i.e., documentation patient is at Risk of Self-Harm, recent Suicide History). *Requires collaborative management and information sharing across different teams and systems. *Requires clinical staffing management to ensure prescriber and nursing time is adequate to meet patient care delivery needs.</p>
10. Informed Consent & Right to Refuse G-05 (I)	0.0% (0/9)	0	8	0.0% (0/8)	<p>8 of 8 files non-compliant: Inconsistent “Medication Refusal” forms for scheduled medication(s) on multiple dates as required per policy requirements (HCD-110_G-05) and inconsistency with refusal details documented on MAR (“Deputy body camera”). <u>Patient 2:</u> ALVESCO, ALBUTEROL HFA. <u>Patient 4:</u> OLANZAPINE. <u>Patient 5:</u> OLANZAPINE. <u>Patient 6:</u> DIVALPROEX SODIUM. <u>Patient 7:</u> BUPRENORPHINE HCL, ESCITALOPRAM, OLANZAPINE, PANTOPRAZOLE SODIUM. <u>Patient 9:</u> MIRTAZAPINE. <u>Patient 14:</u> PROPRANOLOL, DULOXETINE. <u>Patient 15:</u> OLANZAPINE, MIRTAZAPINE. <u>Risk for non-compliance:</u> *Requires collaborative management and information sharing across different teams and systems *Requires clinical staffing management to ensure prescriber time adequate to meet patient specialty care delivery needs</p>

MEDICAL RECORD REVIEW: OBSERVATIONS AND RECOMMENDATIONS DETAILS

I. Section A – Governance and Administration

<p>1. Access to Care A-01 (E)</p> <p>Are the relevant problems/alerts appropriately identified?</p>	<p><u>Observation:</u> Access to care means that the patient is seen by a qualified health care professional, is rendered an appropriate clinical judgment, and receives care that is ordered. Complete and accurate problem lists, as well as clinically indicated alerts, help eliminate intentional and unintentional barriers to care access and delivery. Problem Lists were not consistently started, completed, or up to date for all of the applicable patient files reviewed. Clinically relevant acute and chronic diseases, such as, but not limited to, “Hypertension,” “Diabetes Mellitus,” “Bilateral Below the Knee Amputation,” “Hyperthyroidism,” “Chronic Back Pain,” “Obesity,” “Pregnant,” “Venous Stasis Ulcer,” “Gastroesophageal Reflux Disease,” “Lice,” “Trichomoniasis,” “Thrombocytopenia,” “Polycythemia,” “Failure to Thrive,” “Self-Harm Behavior/Self-Injury,” “Gravely Disabled,” “Bipolar Disorder,” “Depression,” “Developmental Disability,” “Schizophrenia,” were not listed on the Problem List; some were missing or documented later throughout the patient’s booking. Additionally, clinically indicated Alerts were inconsistently added for some of the applicable patient files reviewed, such as “ADA/Special Needs,” “Medical Isolation,” “Suicide Watch,” “Lower Level/Lower Bunk Restriction – Mobility Impairment,” “Diversion – Palming/Cheeking/Hoarding Pills.” Care coordination and collaborative management across the different teams are required, to assure all patient Problems and Alerts, including medical and behavioral health, are identified, and managed appropriately. Without a complete and accurate Problem List and Alert Ribbon, there is an increased risk for inadequate care, inappropriate care, and delayed care, which could result in patient injury and/or harm.</p>
<p>2. Grievance Process for Health Care Complaints A-10 (I)</p> <p>Is the inmate grievance(s) timely, based on principles of adequate medical care, and supporting documentation?</p>	<p><u>Observation:</u> The grievance process is measured against the principles of adequate and timely medical care and complete supporting documentation. Forvis Mazars observed inconsistent documentation to support delayed grievance notification to medical, linkage to patient sick call refusals, medical response, and mental health coordination, for one of the applicable patient files reviewed. Addressing the medical complaint and grievances adequately and timely are required to mitigate patient harm. A comprehensive approach to address patient grievances helps ensure the patient concerns are addressed holistically and that care is well-coordinated, which is particularly important for patients with comorbid conditions.</p>

Governance and Administration Recommendation:

Process:

- Continue Corrective Action Plan (CAP) implementation to ensure compliance with problem lists and alerts, as outlined in Wellpath CAP response:
 - ITR training guidelines.
 - Nursing checklists.
 - Provider checklists.
 - CQI review to measure performance.
- Continue Improvement Plan implementation to:
 - Refine multidiscipline grievance processes to minimize information gaps, duplicative work, and ensure timely resolution.
 - Formalize and socialize updated grievance process, including new staff involvement, streamlined triage, time frames, and escalation process with inmates and all teams, as applicable.
 - Ensure Wellpath policy and procedure are in alignment with the ACSO and updated annually.
 - Redesign the Grievance process to ensure timely access to care and mitigate risk for delayed care. Wellpath and ACSO designees align policy and procedures and update annually. At a minimum, the grievance policy must include a timeframe for response, process for appeal, in accordance with applicable state and accreditation requirements.
 - Implement low-cost technology solution Robotics Processing Automation (RPA) to eliminate manual entry and operational waste.
- Continue to include the Grievance Process as a part of the CQI Program:
 - Track and trend grievances to identify recurrent issues and implement corrective action if indicated.
 - Ensure grievances are reviewed annually at a minimum, however Forvis Mazars recommends more frequent intervals if a trend is identified.
- Continue to review documentation against any related video surveillance to investigate grievance information gaps, as applicable.
- Develop and implement workflow checklists and standardized practices (i.e., chronic, and/or new problems/diagnoses and alerts, pathophysiological states, potentially significant abnormal physical signs and laboratory findings, disabilities, and/or unusual conditions), and include relevant clinical information from outside facility and hospital medical clearance/discharge summaries.
- Continue multi-disciplinary partnerships to improve care coordination: Wellpath medical, ACSO corrections, AFBH behavioral health, and Maxor pharmacy, to uniformly manage and share information across teams and systems.
- Reassess clinical staffing plan to ensure prescriber and nursing time is sufficient to meet patient care delivery needs.

MEDICAL RECORD REVIEW: OBSERVATIONS AND RECOMMENDATIONS DETAILS

Technology:

- To eliminate clinically relevant information gaps and help mitigate human error from manual entry, work closely with Wellpath Corporate IT to submit relevant change requests timely to configure existing CorEMR modules and controls.
- Implement enhanced data integration solution(s) for bidirectional information sharing across applicable systems beyond current interfaces, between Wellpath medical (CorEMR), ACSO corrections (ATIMS), Adult Forensic Behavioral Health (AFBH) behavioral health (Gateway), and Maxor pharmacy (Guardian).

II. Section E – Patient Care and Treatment

<p>3. Receiving Screening E-02 (E)</p> <p>Is the receiving screening form completed appropriately and timely?</p>	<p><u>Observation:</u> Receiving Screening should be performed as soon as possible on all inmates upon arrival at intake to ensure that emergent and urgent health needs are met. Appropriate and timely receiving screening intends to identify potential emergency situations among new arrivals and ensures that patients with known illnesses and those on medications are identified for further assessment and continued treatment. Some of the applicable patient files reviewed showed inconsistent and delayed Intake/Admission Screening documentation beyond 8-hours from the applicable Book-In time. Outdated “Retired Receiving Screening” forms were observed to be used. Some of the applicable patient files reviewed showed Receiving Screening forms not started. Use of screening forms excluding mental health details, including documentation referring to the AFBH clinician’s responsibility to perform the mental health section of the screening, use of a new form “Receiving Screening Alameda OTP without MH,” or scanned AFBH “Assessment Initial Brief” document was not consistent. Without appropriate, timely, up to date, and consistent Receiving Screening assessments, the Clinical Team cannot establish an adequate and individualized care plan to responsibly care for the patient, identify and assure patient health care needs are met, and meet applicable policy, procedure, and standards requirements.</p>
<p>4. Initial Health Assessment E-04 (E)</p> <p>Is the IHA completed within 14 calendar days? If not, is the patient refusal form completed correctly and timely?</p>	<p><u>Observation:</u> While there is improvement from the prior month, evidence of compliance with the requirement to initiate and/or complete the IHA within 14-calendar days of a patient’s intake to the facility was missing or untimely or incomplete for most of the applicable patient files reviewed. All inmates should receive Initial Health Assessments (IHA). Additionally, evidence of related scanned patient refusals was not consistent. Without a complete and/or timely initial medical history and physical exams, the Clinical Teams cannot establish an appropriate and individualized care plan to responsibly care for the patient, appropriately identify and assure patient health care needs are met, and meet applicable policy, procedure, and standards requirements.</p>
<p>5. Nonemergency Health Care Requests & Services E-07 (E)</p> <p>Is there evidence that the patient was seen within 24 hours of the patient sick call request?</p>	<p><u>Observation:</u> Nursing Assessments related to patient health care/sick call requests were not consistently timely for some of the applicable patient files reviewed – patients were classified as non-compliant if half or more (>= 50%) of the nursing assessments reviewed were performed beyond the required 24-hour turnaround time, per applicable policies. All patient nonemergent health care needs should be met and prioritized. All inmates, regardless of housing, should be given the opportunity to submit health care/sick call requests. Additionally, some of the patient Sick Call Requests continue to be miscategorized and not consistently named. Inability to respond timely and document the date the assessment and related care was provided, and/or inconsistent naming convention increases the risk of inadequate care, inappropriate care, delayed care, and uncoordinated care, which could negatively impact patient outcome(s) and result in patient injury and/or harm.</p>
<p>6. Continuity, Coordination, & Quality of Care E-09 (E)</p> <p>Is patient medical, dental, and mental health care coordinated and monitored from admission to discharge?</p>	<p><u>Observation:</u> For patients with Bilateral Below Knee Amputation, falls present a higher risk for injury and thereby require close monitoring to assess additional trauma, pain, and skin integrity. Community clinical standards and guidelines recommend that the patient’s vital signs are taken immediately after a fall to assess for any acute changes or signs of distress, and follow-up monitoring at regular intervals to ensure the patient is stable. For one of the applicable patient files reviewed, Forvis Mazars observed incomplete patient assessments status post an unwitnessed patient fall, with no evidence of documented vital signs immediately after the reported fall, and inconsistent follow-up monitoring. Patient medical, dental, mental health, and specialty care should be coordinated and monitored from Book-In to release. The delivery of coordinated care, such as continuity of care upon “Return from Off-Site Care Visit,” “Orthopedic,” “Physical Therapy,” “Dental,” “Wound Care,” and medication management, were inconsistent or delayed for some of the applicable patient files reviewed. Evidence of “Mental Health” referral outcomes visible within CorEMR, and incomplete Return from Off-Site Care Visit documentation continues to be inconsistent. The inability to provide appropriate and timely care in accordance with community clinical standards and guidelines, increases the risk for inadequate care, inappropriate care,</p>

	<p>delayed care, and uncoordinated care, which could negatively impact patient outcome(s) and result in patient injury and/or harm.</p>
<p>7. Discharge Planning E-10 (E)</p> <p>Is discharge planning provided for inmates with serious health needs?</p>	<p><u>Observation:</u> Discharge planning consults were inconsistent or delayed for some of the applicable patient files reviewed. Discharge planning should be provided for patients with serious health needs, including making formal linkages between the facility and community-based organizations (CBO), lists of community health professionals, discussions with patients that emphasize the importance of appropriate follow-up and aftercare, appointments and medications arranged for the patient at release, and timely exchange of health information. The inability to provide adequate discharge planning in accordance with industry standards and best practice increases the risk for inadequate care, inappropriate care, delayed care, and uncoordinated care, which could negatively impact patient outcome(s) while incarcerated and when released into the community, and result in patient injury and/or harm.</p>
<p>Patient Care and Treatment Recommendation:</p> <p>Process:</p> <ul style="list-style-type: none"> • Continue CAP implementation to ensure compliance with IHA within the required 14-day timeframe, as outlined in Wellpath CAP response: <ul style="list-style-type: none"> ○ History and Physical process development and enhancement. ○ Staff training. ○ CQI review to measure performance. • Continue CAP implementation to ensure compliance with the nonemergency health care requests for services, as outlined in Wellpath CAP response: <ul style="list-style-type: none"> ○ Medical request process development and enhancement. ○ Staff training. ○ CQI review to measure performance. • Continue Improvement Plan implementation to: <ul style="list-style-type: none"> ○ Consistently perform complete Receiving Screening assessments appropriately and timely, as required at intake, with the use of checklists and updated screening forms. In the event a Receiving Screening is not possible, require justification documentation and the timely completion of an Abbreviated Receiving Screening form. ○ Require appropriate and timely care delivery to meet community clinical standards and guidelines, including the review of case studies with the Clinical Team as a part of continuous improvement activities. ○ Require the delivery of timely, coordinated discharge planning, including California Advancing and Innovating Medi-Cal (CalAIM) initiatives, as required by policy and best practice, in collaboration with the multidisciplinary teams. ○ Develop a list of justification reasons to reschedule an appointment, socialize, and implement across all disciplines. • Hold Clinicians accountable for the notification, delivery, and documentation of medically necessary care. • Provide additional focused staff training and education, as applicable. • Perform ongoing internal auditing and monitoring of care delivery appropriateness, timeliness, and care coordination, as well as Sick Call follow-up and clinical Tasks, as applicable. Consider including it in the existing Provider chart review process. Report results of auditing and monitoring to ACSO. • Continue multi-disciplinary partnerships to improve care coordination: Wellpath medical, ACSO corrections, and AFBH behavioral health, to uniformly manage and share information across teams and systems. • Reassess clinical staffing plan to ensure prescriber and nursing time is sufficient to meet patient care delivery needs. <p>Technology:</p> <ul style="list-style-type: none"> • To eliminate clinically relevant information gaps and help mitigate human error from manual entry, work closely with Wellpath Corporate IT to submit relevant change requests timely to configure existing CorEMR modules and controls. • Implement enhanced data integration solution(s) for bidirectional information sharing across applicable systems beyond current interfaces, between Wellpath medical (CorEMR), ACSO corrections (ATIMS), Adult Forensic Behavioral Health (AFBH) behavioral health (Gateway), and Maxor pharmacy (Guardian). 	
<p>III. Section F – Special Needs and Services</p>	
<p>8. Patients With Chronic Disease & Other Special Needs F-01 (E)</p> <p>Is the patient with chronic disease assessed at least every 90 days with an updated treatment plan?</p>	<p><u>Observation:</u> Patients with chronic diseases and other significant health conditions, and disabilities should receive ongoing multidisciplinary care aligned with evidence-based standards. Chronic Care referrals were missing when the clinical need was identified at Book-In and throughout the patient's booking for some of the patient files reviewed. Inconsistency in the identification of chronic care and special needs and related development of individualized treatment plans increases the risk for inadequate care, inappropriate care, delayed care, and/or uncoordinated care, which could negatively impact patient outcome(s), re-entry into the community, and result in patient injury and/or harm.</p>

Special Needs and Services Recommendation:

Process:

- Continue Improvement Plan implementation to:
 - Require appropriate and timely care delivery, include the review of case studies with the Clinical Team as a part of continuous improvement activities.
 - Require the delivery of timely, coordinated chronic care and special needs services in collaboration with the multidisciplinary teams.
 - Develop a list of justification reasons to reschedule an appointment, socialize, and implement across all disciplines.
 - Hold Clinicians accountable for the notification and delivery of medically necessary care.
 - Continue to provide additional focused staff training and education to assure the appropriate services are provided and define individual care plans.
 - Perform ongoing internal auditing and monitoring of care delivery appropriateness, timeliness, care coordination, as well as Sick Call follow-up and clinical Tasks, as applicable.
 - Continue multi-disciplinary partnerships to improve care coordination: Wellpath medical, ACSO corrections, AFBH behavioral health, and Maxor pharmacy, to uniformly manage and share information across teams and systems.
 - Reassess clinical staffing plan to ensure prescriber and nursing time sufficient to meet patient care delivery needs.

Technology:

- Work closely with Wellpath Corporate IT to submit relevant change requests timely to enhance existing CorEMR automation to populate relevant documentation within the applicable forms and/or MAR.
- Implement enhanced data integration solution(s) for bidirectional information sharing across applicable systems beyond current interfaces, between Wellpath medical (CorEMR), ACSO corrections (ATIMS), Adult Forensic Behavioral Health (AFBH) behavioral health (Gateway), and Maxor pharmacy (Guardian).

IV. Section G – Medical: Legal Issues

<p>9. Restraint and Seclusion & Segregated Inmates G-01 & G-02 (E)</p> <p>For the patient at risk for self-harm, was health monitoring initiated timely, and continued at medically appropriate intervals?</p>	<p><u>Observation:</u> Segregated patients should be monitored timely, at initiation and at continued medically appropriate intervals to assure the patient is not harmed by the intervention. Any practice of restraint, seclusion, and segregation should not adversely affect a patient's health. Some of the applicable patient files reviewed showed inconsistent use of patient monitoring Flow Sheets as indicated for the risk of patient Self-Harm Behavior/Self-Injury. Delay or inconsistent initiation of patient monitoring Flow Sheets, including "Sobering/Safety/Restraints" or "Nursing Segregated Population Rounding Log" Flow Sheets, when the patient requires close monitoring for Suicide Attempt, Suicidal Ideation, or Suicide History, increases the risk for a safety incident, including patient injury and/or harm. Further, the multidisciplinary teams cannot evidence compliance with policies (8.12 Inmate Observation and Direct Visual Supervision; 8.13 Safety Cells, Temporary Holding Cell, and Multipurpose Rooms; HCD-110_G02 Segregated Inmates), and applicable standards.</p>
<p>10. Informed Consent & Right to Refuse G-05 (I)</p> <p>If the patient refuses medications, did the refusal documentation include evidence that the patient has been informed and understands any adverse health consequence that may occur because of refusal?</p>	<p><u>Observation:</u> Inmates have the right to make informed decisions regarding health care, including the right to refuse. All the applicable patient files reviewed showed inconsistency and/or missing required patient refusal forms for medication administration. Forvis Mazars found that some of the patient files reviewed showed inconsistency in the scanning of patient medication refusals for chronic medication management, specifically missing medication refusals or scanning delays beyond 48-hours, contributing to medication inconsistencies with the MAR. Without complete and timely scanning of priority medical records, such as patient medication refusals, the Clinical Teams cannot responsibly identify a pattern of refusal and follow established refusal policy and protocol: "In the case of medication refusals, in addition to a signed refusal form, documentation on the MAR will indicate the patient refused the medication. Scheduled Routine Medications: If a patient misses four doses in a seven-day period, or establishes a "pattern of refusal," the patient is referred to the prescribing Provider. The referral is submitted after the fourth missed dose," (HCD-110_G-05 Informed Consent and Right to Refuse) to manage the risk factors for medication nonadherence. Inconsistent medication management, including conflicting medication administration vs. patient refusal documentation and evidence, can lead to a medication error, such as a missed medication dose and result in patient injury, harm, and/or grievance. Additionally, without evidence of patient refusals to show that the patient was provided education and understands the risks involved with not being evaluated or treated, there is an increased risk for patient injury and/or harm, as well as organizational risk.</p>

Medical: Legal Issues Recommendation:

Process:

- Continue Improvement Plan implementation to:
 - Require appropriate and timely care delivery, include the review of case studies with the Clinical Team as a part of continuous improvement activities.
 - Require timely patient assessment and monitoring as ordered and per policy, with supporting justification documentation if unable to execute.

- Define, formalize, communicate, and implement enhanced patient observation, direct supervision, safety cell, and segregated population processes across the impacted teams and follow-up to assess implementation. Update policies and procedures accordingly.
 - Clearly align defined Level of Care considerations and interventions, as applicable, for patients requiring ongoing monitoring.
 - Assure medication refusal protocol described in HCD-110_G-05 Informed Consent and Right to Refuse policy is followed, including real-time communication and documentation.
 - Hold Clinicians accountable for the notification, delivery, and documentation of medically necessary care.
 - Provide additional focused staff training and education, as applicable.
 - Continue to review documentation against any related video surveillance to investigate medication administration grievance information gaps, as applicable.
 - Perform ongoing internal auditing and monitoring of care delivery appropriateness, timeliness, and care coordination, as well as Sick Call follow-up and clinical Tasks, as applicable. Consider including in the existing Provider chart review process. Report results of auditing and monitoring to ACSO.
 - Continue multi-disciplinary partnerships to improve care coordination: Wellpath medical, ACSO corrections, and AFBH behavioral health, to uniformly manage and share information across teams and systems.
 - Reassess clinical staffing plan to ensure prescriber and nursing time is sufficient to meet patient care delivery needs.
- Technology:**
- To eliminate clinically relevant information gaps and help mitigate human error from manual entry, work closely with Wellpath Corporate IT to submit relevant change requests timely to configure existing CorEMR modules and controls.
 - Work closely with Wellpath Corporate IT to submit relevant change requests timely to enhance existing CorEMR automation to populate relevant documentation within the applicable forms and/or MAR.
 - Implement enhanced data integration solution(s) for bidirectional information sharing across applicable systems beyond current interfaces, between Wellpath medical (CorEMR), ACSO corrections (ATIMS), Adult Forensic Behavioral Health (AFBH) behavioral health (Gateway), and Maxor pharmacy (Guardian).

ON-SITE CLINICAL VISIT(S): OBSERVATIONS AND RECOMMENDATIONS

V. Continuous Quality Improvement Inter-Rater Reliability

Observation: During the Clinical Observation onsite visit 6/19/2024 – 6/20/2024, Forvis Mazars continued to work with the Wellpath Quality Assurance Coordinator to review and align Continuous Quality Improvement (CQI) Program activities, with a focus on Inter-Rater Reliability (IRR) CQI across studies.

V.1. Evidence:

- V.1.1.1. To facilitate collaboration, Forvis Mazars provided an overview to the Wellpath Quality Assurance Coordinator's virtual quality support staff leaders (Zenovacare), describing Forvis Mazars' partnership with Wellpath to support CQI monitoring activities, performance improvement strategies, and change implementation effectiveness.
 - V.1.1.1.1. Forvis Mazars revisited the relationship between IRR and CQI, as IRR plays an integral role in ensuring the consistency and accuracy of reviews, vital for the success of CQI initiatives:
 - V.1.1.1.1.1. Ensures consistency in assessments.
 - V.1.1.1.1.2. Validates data for improvement initiatives.
 - V.1.1.1.1.3. Intended to enhance training and process optimization.
 - V.1.1.1.1.4. Support benchmarking and accountability.
 - V.1.1.1.1.5. Drive data-driven decision making.
 - V.1.1.1.2. Forvis Mazars requested to continue the conversations to work regularly with the Wellpath Quality Assurance Coordinator, with the inclusion of the Zenovacare staff performing the CQI study audits to achieve IRR:
 - V.1.1.1.2.1. Ensure uniformity.
 - V.1.1.1.2.2. Improve data quality.
 - V.1.1.1.2.3. Validate reviews.
 - V.1.1.1.2.4. Ensure compliance.
 - V.1.1.1.2.5. Identify training gaps.
 - V.1.1.1.2.6. Help establish and foster feedback for continuous improvement.
 - V.1.1.1.2.7. Follow-up working sessions with Zenovacare pending.

V.2. Recommendations:

- V.2.1. Continue to work collaboratively with Wellpath Quality Assurance Coordinator and meet regularly to achieve IRR, with the working session goals to include, but not limited to:
 - V.2.1.1. Data collection methodology for each CQI measure.
 - V.2.1.2. Understand and align audit approach for each CQI measure.
 - V.2.1.3. Review multiple patients collectively for each CQI measure.
 - V.2.1.4. Clarify the process for providing responses to the questions associated with each CQI audit measure.
 - V.2.1.5. Clarify where in CorEMR relevant information is found.
 - V.2.1.6. Review current Wellpath protocols and identify applicability and whether updates are required.
 - V.2.1.7. Confirm the process for escalating critical quality issues to leadership.
- V.2.2. Continue to work collaboratively to ensure audit alignment and IRR (i.e., consistent patient sampling, consistent audit questions) for an accurate examination of change implementation effectiveness and long-term performance of the improvement strategy, consistent with the widely used Plan-Do-Study-Act (PDSA) model:
 - V.2.2.1. Plan – Plan a change or test aimed at an identified problem: Wellpath CQI study calendar by month, date range for data collection, and criteria questions specific to plan details.
 - V.2.2.2. Do – Carry out the change or test: initial Wellpath CQI study audit and evaluation.
 - V.2.2.3. Study – Analyze the results of the CQI study to learn opportunities of improvement: Wellpath improvement Plan development, implementation, and re-evaluation for initial overall compliance performance of less than 90-95% compliance threshold.
 - V.2.2.4. Act – Run through the cycle again to determine adopt or abandon change: Forvis Mazars CQI review to identify additional risks for non-compliance and need for corrective action plan (CAP).

APPENDIX

PROJECT DETAILS

Project Scope

Assess and evidence the County and ACSO compliance with complex requirements applicable to Alameda County's Santa Rita Jail (SRJ) adult correctional facility and to evaluate quality of care provided by Wellpath. Additionally, evaluate the County's compliance with applicable laws, rules, and regulations of applicable government authorities regarding the ambulatory medical care provided to incarcerated individuals (patients) at SRJ and required by the ACSO. Project scope excludes the provision of any direct patient medical care.

METHODOLOGY

A. MEDICAL QUALITY ASSURANCE MEDICAL RECORD REVIEW

As described in Exhibit A-1 of the Master Services Agreement (MSA), Forvis Mazars conducted monthly medical record review of patient medical records to evaluate the timeliness of care, appropriateness of assessment, treatment, type of Provider and level of care, within the specified populations and areas of focus. Forvis Mazars performed the following quality assurance related activities:

- Evaluated 15 patient files for the reporting period, as applicable:
 - Death: Patient death/mortality.
 - Suicide: Patients who attempted suicide, with history of suicide, or reported suicidal ideation.
 - Hospital Transport and Admission: Patients emergently transported to a hospital for evaluation, and/or inpatient admission, and/or for an Outpatient Specialist appointment.
 - Grievances: Patients with medical grievances.
 - Women's Health, OBGYN Services: Female patients under Women's Health, OBGYN care.
- Tested patient files against compliance indicators, such as, but not limited to, access, appropriateness, continuity, and timeliness of care delivery, and compliance with applicable requirements and evidence-based best practice, including, but not limited to facility and medical policies and procedures, National Commission on Correctional Health Care (NCCHC), American Correctional Standards (ACA), California Code of Regulations, and community standards of care.
- Compliance indicators are as follows:
 1. **Access to Care** – Are the relevant problems/alerts appropriately identified?
 2. **Grievance Process for Health Care Complaints** – Is the inmate grievance(s) timely, based on principles of adequate medical care, and supporting documentation?
 3. **Receiving Screening** – Is the receiving screening form completed appropriately and timely?
 4. **Initial Health Assessment** – Is the IHA completed within 14 calendar days? If not, is the patient refusal form completed correctly and timely?
 5. **Nonemergency Health Care Requests and Services** – Is there evidence that the patient was seen within 24 hours of the patient sick call request?
 6. **Continuity, Coordination, and Quality of Care** – Is patient medical, dental, and mental health care coordinated and monitored from admission to discharge?
 7. **Discharge Planning** – Is discharge planning provided for inmates with serious health needs?
 8. **Patients With Chronic Disease and Other Special Needs** – Is the patient with chronic disease assessed at least every 90 days with an updated treatment plan?
 9. **Restraint and Seclusion & Segregated Inmates** – For the patient at risk for self-harm, was health monitoring initiated timely, and continued at medically appropriate intervals?
 10. **Informed Consent and Right to Refuse** – If the patient refuses medications, did the refusal documentation include evidence that the patient has been informed and understands any adverse health consequence that may occur because of refusal?
- Performed clinical observations and provided corresponding observations and recommendations.

Additional considerations:

- For the medical quality assurance (QA) reporting period*, Forvis Mazars conducted medical record review of 15 incarcerated individual (patient) files for the specified high-risk populations and areas of highest concern, consistent with contract requirements. The files reviewed were limited to include the patients discussed during the weekly Multi-Disciplinary Round (MDR) meetings and patients selected from scheduled monthly reports including the suicide attempt report, the medical grievance report, the OBGYN Report, and the transportation/hospitalization report, for the specified reporting period.
 - *The "reporting period" refers to the month that patient files were selected from the specified populations and areas of focus noted above. To adequately evaluate timeliness of care, appropriateness of assessment, treatment, type of Provider and level of care, Forvis Mazars reviewed each patient's medical record booking from Book-In to Release. For patients that were determined to be in custody for multiple years, intake details, care provided during the current year, and release details were reviewed.

METHODOLOGY

- While the sample size of 15 is not statistically significant when compared to the overall population size, the sampling methodology is designed to select specified patient populations and areas of highest concern as identified within the MSA.
- Observations that overlap across multiple focus areas were considered non-compliant for the compliance indicator that most impacted patient care delivery; the observation was noted as a “Risk for non-compliance” for all other areas.
- The compliance threshold goal for QA review is consistent with the compliance threshold for the related CQI studies, as follows:
 - 90% compliance threshold goal:
 1. Access to Care.
 2. Grievance Process for Health Care Complaints.
 4. Initial Health Assessment.
 5. Nonemergency Health Care Requests and Services.
 7. Discharge Planning.
 9. Restraint and Seclusion & Segregated Inmates.
 - 95% compliance threshold goal:
 3. Receiving Screening.
 6. Continuity, Coordination, and Quality of Care.
 8. Patients With Chronic Disease & Other Special Needs.
 10. Informed Consent and Right to Refuse.
- A compliance score of less than 90-95% warrants a Corrective Action Plan (CAP). Areas at risk for non-compliance, requiring collaborative management and information sharing across different teams and systems, and adequacy of clinical staffing were also identified.
- Quality assurance not only measures compliance with standards and mitigates risk, but also includes the follow-up on corrective action plan activities, facilitates accountability, and informs quality improvement processes. Forvis Mazars thereby identifies linkages between quality assurance and continuous quality improvement observations.

B. MINOR AND MAJOR ERROR(S)

To observe any minor or major error in medical care, Forvis Mazars performed the following activities, as applicable:

- Outlined the circumstances of the error.
- Proposed recommendations for corrective action.
- Followed-up on corrective action implementation, as applicable.

C. PATIENT DEATH(S), SUICIDE, AND ATTEMPTED SUICIDE

To review medical records for patient death(s), Forvis Mazars performed the following activities:

- Reviewed medical care provided to patient prior to death.
 - Reviewed documentation, as applicable, following death, including 30-Day and 120-Day death reviews (Death review meetings)
- To review medical records for patient(s) who were reported as having attempted suicides, Forvis Mazars performed the following activities:
- Reviewed occurrence of suicide attempt.
 - Reviewed medical care provided following suicide attempt, including suicide prevention strategies and multidisciplinary care plan (Suicide Prevention meetings).

D. HOSPITAL TRANSPORT AND ADMISSIONS

To review medical records upon patient emergent transport to a hospital for evaluation, and/or inpatient admission, and/or Outpatient Specialist appointment, Forvis Mazars performed the following activities:

- Reviewed occurrence of a patient emergently transported to a hospital for evaluation.
- Reviewed occurrence when a patient is admitted to a hospital, including the circumstances leading to the inpatient admission.
- Reviewed occurrence when a patient is transported to an Outpatient Specialist appointment.

E. GRIEVANCE REVIEW

To evaluate patient medical grievances, Forvis Mazars performed the following activities:

- Reviewed select medical grievance claims for the applicable reporting period to identify larger, systemic medical concerns underlying grievance, as applicable.
- Included patients with medical grievance claims for the reporting period.

F. WOMEN'S HEALTH AND OBGYN SERVICES REVIEW

To evaluate the medical care of female patients, including Women's Health Clinic and OBGYN services, Forvis Mazars performed the following activities:

- Reviewed medical records of female patients under medical care for the reporting period.
- Reviewed medical records of female patients under care of OBGYN clinic in the report period.
- Evaluated compliance with all relevant regulations, standards, and agreements adopted by the ACSO.

G. ON-SITE CLINICAL OBSERVATION VISIT(S)

- Forvis Mazars performed clinical observation for the reporting period and provided related observation details and recommendations.
- As applicable, Forvis Mazars evaluated status of Wellpath medical initiatives not identified as site-specific CQI Studies and provided related observation details and recommendations.

H. CORRECTIVE ACTION PLAN

- As applicable, Forvis Mazars issued a Quality Assurance Corrective Action Plan (CAP) based on identified ongoing issues of non-compliant performance described within the Medical Quality Assurance Monthly Reports.
- QA CAP(s) shall be issued to Wellpath every quarter, as applicable.
- CAP definition, responsibilities, response, and escalation details are described in the Corrective Action Plan procedure and corresponding ACSO Memo.

I. OTHER

- Forvis Mazars provided third-party medical consultation to Wellpath and ACSO on medical issues including the review of medical records, diagnoses, and treatment plans, as well as discussion with those Clinicians providing direct care, as needed.
- Forvis Mazars provided guidance and recommendations, as necessary, related to medical facility licensure, accreditation, treatment protocols, and general medical quality assurance and continuous quality improvement issues.