QUALITY PROFESSIONAL SERVICES COMMITTEE MEETING

Wednesday, July 23, 2025
5:00pm-7:00pm

Conference Center at Highland Care Pavilion
1411 East 31st Street Oakland, CA 94602
Ronna Jojola Gonsalves, Clerk of the Board
(510) 535-7515

LOCATION:
Open Session: HCP Conference Center, see above address

Members of the public may also participate at the following ZOOM Meeting Link:[1]
https://alamedahealthsystem.zoom.us/j/9361457125?pwd=4JnAmhDnBaLqY4GWf4PQBwp3w0Puy2.1&omn=83132933734
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COMMITTEE MEMBERS
Greg Garrett
Lilavati Indulkar, MD, Chair
Donna Linton
Nicholas Moss, MD

NON-VOTING MEMBERS
Chief of Staff – AHS Medical Staff
Chief of Staff - AH Medical Staff

[1] Log into the meeting at www.zoom.com. You will be directed to download the meeting app (free) if you have not used ZOOM previously. ZOOM meetings may be accessed on computers and portable devices.

NOTE: In the event that a quorum of the Board of Trustees participates on this Committee, the meeting is noticed as a Special Meeting of the Board of Trustees; however, no final Board of Trustees action can be taken.

QUALITY PROFESSIONAL SERVICES COMMITTEE MEETING AGENDA

SPECIAL NOTE: Per Brown Act requirements, Trustees of the Alameda Health System will attend board and committee meetings in person at the location(s) noticed on this agenda. Staff and members of the public may attend either in person at the location noticed on this agenda, or remotely via Zoom, using the link included on this agenda.

Public Comment Instructions
If you attend the meeting in person and wish to address the Board or Committee regarding an item on the agenda or in their purview, please see the Clerk of the Board to sign up.

If you attend the meeting remotely and wish to address the Board of Trustees or Committee regarding an item on the agenda or in their purview, send an email to cob@alamedahealthsystem.org prior to the start of the meeting, or via Zoom chat during the meeting. Your comment will be heard at the appropriate time.

Each speaker, whether in person or remote, will be allotted between one and three minutes to speak, depending on the number of speakers present.

OPEN SESSION / ROLL CALL

PUBLIC COMMENT

A. DISCUSSION: Clinical Highlights
Lilavati Indulkar, MD, Chair

B. ACTION: Consent Agenda

B1. Approval of the Minutes of the June 25, 2025 Quality Professional Services Committee Meeting

B2. Recommendation to the Board of Trustees for approval of the System Wide Policies:

- Highland Hospital 340B Policy
- Alameda Hospital 340B Policy
- Alameda Health System-Freestanding Clinics 340B Policy
- AVOIDING DUPLICATE PRN “As Needed” POLICY
- MEDICATIONS SELF-ADMINISTRATION (34361-1)
- MEDICATION KITS TRANSPORT BOXES FOR SPECIFIC DEPARTMENTS AND DIVISIONS (34324-1)
- Highland Hospital Outpatient Pharmacy Quality Assurance and Medication Error Reporting (34359 -1)
- Clinical Practice Council Charter
- AHS Administrative Closure of Incomplete Records 2025

B3. Recommendation to the Board of Trustees for approval of the AHS Medical Staff Policies and Procedures listed below:

AHS and AH Medical Staff:

- Introduction of a New Privilege or New Privilege for a Specific Department or Specialty
- Pain Medicine Anesthesia Standardized Procedure

B4. Approval of the AHS Medical Staff Revised Application Forms and Revised Privilege Forms listed below:

Revised Application Forms for AHS & AH:

- Confidentiality Agreement Form for Remote Meeting Access (revision) – for non-Medical Staff
- Confidentiality Agreement for Medical Staff Affairs (revision) – for Medical Staff/APP inclusion in application/reapplication
- Malpractice Claims History

Revised Privilege Forms for AHS:

- Pain Medicine – Advanced Practice Provider
- Physical Medicine and Rehabilitation Advanced Practice Provider

Recommendation: Motion to Approve

END OF CONSENT AGENDA

C. REPORT/DISCUSSION: Medical Staff Reports
AHS Medical: Berenice Perez, MD, Chief of Medical Staff
AH Medical: Catherine Pyun, DO, Chief of Medical Staff

D. REPORT/DISCUSSION: Quality Reports

D1. Regulatory Affairs, Quality OKR Dashboard
Ana Torres, Vice President, Quality

D2. Post Acute
Richard Espinoza, Chief Administrative Officer, Post Acute

E. DISCUSSION: QPSC Metric Selection and Goal Setting Approval
Beth Mahler, MD, Interim Chief Medical Officer

F. CLOSED SESSION

F1. Consideration of Confidential Medical Staff Credentialing Reports
Chief of Staff, AHS Medical Staff
Chief of Staff, AH Medical Staff

F2. Regulatory Affairs, Risk Management, Patient Safety
[Health and Safety Code 101850(ai) (1)]

(Reconvene to Open Session)

G. OPEN SESSION

REPORT: Legal Counsel's Report on Action Taken in Closed Session
Ahmad Azizi, General Counsel

ADJOURNMENT

ADDENDUMS

- Agenda Item D: OKRS
- Agenda Item D: Post Acute Presentation

Our Mission
Caring, Healing, Teaching, Serving All

Strategic Vision
AHS will be recognized as a world-class patient and family centered system of care that promotes wellness, eliminates disparities and optimizes the health of our diverse communities.

Values
Compassion, Commitment, Teamwork, Excellence, Integrity, and Respect.

Meeting Procedures
All items appearing on the agenda are subject to action by the Board of Trustees. Staff recommendations are subject to action and change by the Board of Trustees.

The Board of Trustees is the Policy Body of the Alameda Health System. The Board has several standing Committees where Board matters are the subject of discussion at which members of the public are urged to testify. Board procedures do not permit: 1) persons in the audience at a Committee meeting to vocally express support or opposition to statements by Board Members or by other persons testifying; 2) ringing and use of cell phones, pagers, and similar sound-producing electronic devices; 3) signs to be brought into the meeting or displayed in the room; 4) standing in the meeting room. Citizens are encouraged to testify at Committee meetings and to write letters to the Clerk of the Board or to its members, 1411 East 31st Street Oakland, CA 94602.
Members of the public are advised that all Board and Committee proceedings are recorded (audio), including comments and statements by the public in the course of the meetings. Copies of the audio recordings will be made available to the public. Copies of the agendas and supporting documents can be found here: http://www.alamedahealthsystem.org/meeting-agendas-and-minutes/**. By attending and participating in Board/Committee meetings, members of the public consent to audio recording of any statements they may make during the proceedings.**

Disability Access

The Meeting Rooms are wheelchair accessible. Assistive listening devices are available upon request at the Clerk of the Board's Office. To request accommodation or assistance to participate in the meeting, please contact the Clerk of the Board. Requests made at least 48 hours in advance of the meeting will help to ensure availability.
In order to accommodate persons with severe allergies, environmental illness, multiple chemical sensitivity or related disabilities, attendees at public meetings are reminded that other attendees may be sensitive to perfumes and various other chemical-based scented products. Please help us to accommodate these individuals.

The AHS Board of Trustees is committed to protecting the private health information (PHI) of our patients. We ask that speakers refrain from disclosing or discussing the PHI of others. Please also know that, should you decide to disclose your PHI, the Trustees will still likely refer your matter, to the extent it involves PHI, to the executive staff for a confidential review of the facts and for confidential handling. If you would like more information regarding the confidentiality of PHI as it relates to the Health Insurance Privacy and Accountability Act, please refer to 45CFR Section 164.101, et.seq.

B1. Approval of the Minutes of the June 25, 2025 Quality Professional Services Committee Meeting

QUALITY PROFESSIONAL SERVICES COMMITTEE MEETING

Wednesday, June 25, 2025
5:00pm-7:00pm

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1411 East 31st Street Oakland, CA 94602
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LOCATION:
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COMMITTEE MEMBERS
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Lilavati Indulkar, MD, Chair
Donna Linton
Nicholas Moss, MD

NON-VOTING MEMBERS
Chief of Staff – AHS Medical Staff
Chief of Staff - AH Medical Staff

QUALITY PROFESSIONAL SERVICES COMMITTEE MEETING MINUTES

THE MEETING WAS CALLED TO ORDER AT 5:04 pm

ROLL CALL WAS TAKEN AND THE FOLLOWING TRUSTEES WERE PRESENT: Lilavati Indulkar, MD, Nicholas Moss, MD, Trustee Sayen (attending as member of the Executive Committee to achieve quorum)

ABSENT: Greg Garrett, Donna Linton, Excused

PUBLIC COMMENT: None

A. DISCUSSION: Clinical Highlights
Lilavati Indulkar, MD, Chair

Trustee Indulkar shared a video from a patient thanking AHS for their care.

Trustee Indulkar spoke to the importance of the whole system around cardiology. This system included collaboration with anesthesia and other physicians, appropriate nurse and technician staffing levels, the physical space, and strong leadership.

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Trustee Sayen said people thought of urgent care when they considered care at AHS. What they wanted to do was get more stories like the one Trustee Indulkar shared from everyone, including people who had non urgent care experiences. Bringing this mindset to everything we do should be the goal.

B. ACTION: Consent Agenda

Trustee Indulkar asked if there was any public comment on the consent agenda, Ms. Jojola Gonsalves said there was not.

B1. Approval of the Minutes of the May 28, 2025 Quality Professional Services Committee Meeting

B2. Recommendation to the Board of Trustees for approval of the System Wide Policies and Standardized Procedures listed below:

- Medication Drug Recall
- Outpatient Pharmacy Dispensing

B3. Recommendation to the Board of Trustees for approval of the AHS Medical Staff Policies and Procedures listed below:

AHS and AH Medical Staff:
- Identifying and Credentialing HIV/AIDS Specialists

AHS Medical Staff:
- Medical Staff Department Structure and Division Leadership
- Introduction of a New Privilege or New Privilege for a Specific Department or Specialty

B4. Approval of the AHS Medical Staff Revised Application Forms and Revised Privilege Forms listed below:

Revised Application Forms for AHS & AH:
- HIV AIDS Specialist Designation Letter and Form

Revised Privilege Forms for AHS:
- Pediatrics – Developmental Behavioral
- Pain Medicine Advanced Practice Provider

Trustee Moss moved and Trustee Sayen seconded to approve the consent agenda.

ACTION: A motion was made and seconded to approve the consent agenda. A roll call was taken, and the motion passed.
AYES: Trustees Indulkar, Moss, and Sayen
NAYS: None
ABSTENTION: None
END OF CONSENT AGENDA

C. REPORT/DISCUSSION: Medical Staff Reports

AHS Medical: Berenice Perez, MD, Chief of Medical Staff
AH Medical: Catherine Pyun, DO, Chief of Medical Staff

Trustee Indulkar said she wanted more information on how the challenges listed in the presentation could become part of the overall operations plan. Dr. Perez said they were looking at the QAPI plan now and that would go a long way. She frequently worked with Dr. Mahler as part of her operational dyad. Dr. Perez said sometimes the chairs were not sure who their dyad was. Making sure that information was clear was important.

Trustee Sayen spoke to the practical nature of busy physicians sitting on so many committees. As practical matter physicians didn't have time to do some of these control tasks. Dr. Perez said many wanted to be on these committees. Helping to find the balance between what they want operationally and how that impacts patient care was important. Many committees on this quality assurance plan were chaired by one or two physicians.

Trustee Moss said by the time things got to the Board for votes they were pretty mature. This would not be the only time physicians would hear the issue.

Trustee Sayen asked about capitation for the assigned unseen patients. Dr. Mahler said it wasn't global. They were capitated for certain things. Mr. Jackson said they've had conversations with the Alliance regarding why they should continue to pay us a capitated rate if the patients were not being seen by us.

Trustee Moss asked if all the assigned unseen patients could get appointments. Dr. Mahler said no. Dr. Mack said the Alliance data as a whole was about 33.3% assigned unseen. We were not far off that mark and were trending down. The goal was to get closer to that 33.3%.

Trustee Indulkar asked at what point does a patient become categorized as seen. Dr. Mack said they had to actually be seen. With Medicare, the initial visit had to be in person. They had more leeway with non Medicare patients and could use telecare.

Trustee Moss asked if the new utilization data was for ambulatory only or for all visits. Dr. Mack said utilization was assigned to us and used our primary care services. Assigned unseen included the patients who only used acute care services at AHS or elsewhere.

D. REPORT/DISCUSSION: Quality Reports

D1. Regulatory Affairs, Quality OKR Dashboard

Ana Torres, Vice President, Quality

Trustee Indulkar asked for a highlight on the strategies in place for Hospital Acquired Pressure Injuries (HAPI) and Surgical Site Infections (SSI) that may allow for improvement. Ms. Torres said there was a lot of education taking place. They joined NDNQI, a national nursing quality database to allow for quarterly prevalence rounds. The increase in HAPIs was a result of adding the reporting of stage one events, which was not reported previously. Mr. Fitzgerald Shaw said they have been working on earlier identification of pressure injuries and identifying when they are community acquired verses hospital acquired. They have also been putting the wound care nurses into more of a triage

process so that once these patients were identified, the wound care nurse could come in, assess, and categorize a stage.

Trustee Moss asked if there were similar processes being implemented for SSI. Ms. Torres said they started looking at documentation issues. They discovered that there were issues with capturing data when patients came in with an infection already growing.

D2. Post Acute
Richard Espinoza, Chief Administrative Officer, Post Acute

E. DISCUSSION: Ambulance Patient Offload Times (APOT)
Andrea Wu, MD, Associate Chief Medical Officer Highland

Trustee Moss asked about the consequences of not meeting the offload times required by AB40. Dr. Hodroge said there has not been anything definite. This was a County wide problem. There has been a loose conversation around specialty designations in emergency rooms, but that would potentially make the problem worse. Dr. Bascome said the only reference AB40 had regarding consequences was that if APOT times were not met, biweekly meetings with EMS would be required. The biggest issue at San Leandro was volume versus patient rooms. Mr. Fitzgerald Shaw said one of the biggest bottle necks at Highland was getting patients out of the ED and into the designated areas. They've been talking about the system wide surge plan, including transferring to other campuses.

Trustee Indulkar asked where they have gained traction. Dr. Bascome the Provider Rapid Medical Evaluation worked very well at Highland. Nurses were quick to screen those patients and knew they were able to grab a physician and determine if the patient was able to get off the gurney and go to the waiting room. Trustee Indulkar asked if it was sustainable. Dr. Perez said it was sustainable, but there were only so many patients who could go to the waiting room. Dr. Hodroge said this worked well for San Leandro as well. They also upstaffed on Mondays and Fridays as they were their busy days. He said that the most discharges happen at 4:16pm, but that was when EVS was down staffed, so rooms could not get turned in time to bring more patients in.

Trustee Sayen said there was a fundamental capacity issue. Mr. Fitzgerald said they were evaluating this from the nursing perspective. One barrier was patients needing external resources, there was a long waitlist. Dr. Perez said there were 20-40 patients every day who were ready to leave but did not have a safe landing spot. That often matched the number of patients in the waiting room.

Mr. Azizi said the Quality Committee of the Board would meet in Closed Session to discuss the items as set forth on the agenda.

F. <u>CLOSED SESSION</u>

F1. Consideration of Confidential Medical Staff Credentialing Reports
Chief of Staff, AHS Medical Staff
Chief of Staff, AH Medical Staff

F2. Regulatory Affairs, Risk Management, Patient Safety
[Health and Safety Code 101850(ai) (1)]

(Reconvene to Open Session)

OPEN SESSION

G. REPORT: Legal Counsel's Report on Action Taken in Closed Session
Ahmad Azizi, General Counsel

Mr. Azizi reported that the Committee met in Closed Session and considered credentialing reports for each of the medical staffs and approved credentials/privileges for fully qualified practitioners recommended by the medical staffs.

ADJOURNMENT 7:06 pm

B2. Recommendation to the Board of Trustees for approval of the System Wide Policies_

Alameda Health System			CPC Executive Summary to AHS and AH Medical Executive Committee(s) – July 2025			
Policies and Procedures				Chars: Dr. Bullard & Wacheera Davis		
TOPIC or TITLE OF POLICY	**Document Owners**	**Summary of Changes**	**Last Approved Date**	**Next review date after BOT approval**	**Purpose**	**History of Review Committee**
AHS System Wide Policies & Procedures						
Highland Hospital 340B Policy	Diana Thamrin, PharmD	• Revisions to include MTM services to help facilitate pts receiving medications from other AHS sites • System P&T Approved 6/2025 • Consent Item -PolicyTech		07/2028		• System P&T 6/2025 • CPC 7/03/2025 • MEC 7/16/2025
Alameda Hospital 340B Policy	Diana Thamrin, PharmD	• Revisions to include MTM services to help facilitate pts receiving medications from other AHS sites • System P&T Approved 6/2025 • Consent Item -PolicyTech		07/2028		• System P&T 6/2025 • CPC 7/03/2025 • MEC 7/16/2025
Alameda Health System-Freestanding Clinics 340B Policy	Diana Thamrin, PharmD	• Revisions to include MTM services to help facilitate pts receiving medications from other AHS sites • System P&T Approved 6/2025 • Consent Item -PolicyTech		07/2028		• System P&T 6/2025 • CPC 7/03/2025 • MEC 7/16/2025
AVOIDING DUPLICATE PRN "As Needed" POLICY	Priya Patel, PharmD	• Added minor language revisions to clarify ranking order of duplicate orders • System P&T Approved 6/2025 • Consent Item -PolicyTech		07/2028		• System P&T 6/2025 • CPC 7/03/2025 • MEC 7/16/2025
MEDICATIONS SELF-ADMINISTRATION (34361-1)	Priya Patel, PharmD	• TJC Triennial Review, no changes • System P&T Approved 6/2025 • Consent Item -PolicyTech		07/2028		• System P&T 6/2025 • CPC 7/03/2025 • MEC 7/16/2025
MEDICATION KITS TRANSPORT BOXES FOR SPECIFIC DEPARTMENTS AND DIVISIONS (34324-1)	Priya Patel, PharmD	• Added language on dosing and admin for anaphylaxis treatment per CPC rec's • System P&T Approved 6/2025 • Consent Item -PolicyTech		07/2028		• System P&T 6/2025 • CPC 7/03/2025 • MEC 7/16/2025
Highland Hospital Outpatient Pharmacy Quality Assurance and Medication Error Reporting (34359 -1)	Priya Patel, PharmD	• Minor revisions to align with State Board of Pharmacy Requirements • System P&T Approved 6/2025 • Consent Item -PolicyTech		07/2028		• System P&T 6/2025 • CPC 7/03/2025 • MEC 7/16/2025

Alameda Health System			CPC Executive Summary to AHS and AH Medical Executive Committee(s) - May 2025			
Policies and Procedures				**Chair: Dr. Bullard**		
TOPIC or TITLE OF POLICY	**Document Owners**	**Summary of Changes**	**Last Approved Date**	**Next review date after BOT approval**	**Purpose**	**History of Review Committee**
Incident To Policy	Akemi Renn	• New • To provide the rules when "incident-to" can be used in hospital-based outpatient services in accordance with federal Medicare guidelines		07/2028		• CPC 7/03/2025 • MEC 7/16/2025
Clinical Practice Council Charter	Dr. Kelley Bullard	• Revised		07/2028		• CPC 7/03/2025 • MEC 7/16/2025
AHS Administrative Closure of Incomplete Records 2025	Swaran Dwarka Myesha Griffin	• Revised • Change made: In reference to submitting the list of incomplete records "to the HIM Committee" replaced with "to the appropriate medical staff".		07/2028		• CPC 7/03/2025 • MEC 7/16/2025

ALAMEDA HEALTH SYSTEM

Highland Hospital 340B DRUG PRICING PROGRAM

Site	Alameda Health System	***Previous Revision Dates***	
Effective Date	9/2023	***Date Revised***	Not Approved Yet
Document Owner	MGR SYS MED SAFETY-CLIN PHARM	***Next Scheduled Review***	6/2028

Printed copies are for reference only. Please refer to electronic copy for the latest version.

Purpose

The purpose of this policy is to establish guidance regarding Highland Hospital (HGH) and all child sites' compliance with the rules and regulations set forth by the Health Resources and Services Administration's Office of Pharmacy Affairs ("OPA") pertaining to the Section 340B Drug Discount Program

Background

Section 340B of the Public Health Service Act (1992) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign a pharmaceutical pricing agreement (PPA) with the Secretary of Health and Human Services.

a. This agreement limits the price that manufacturers may charge certain covered entities for covered outpatient drugs.

The 340B Program is administered by the federal Health Resources and Services Administration (HRSA) in the Department of Health and Human Services (DHHS).

Upon registration on 340B OPAIS (Office of Pharmacy Affairs Information System), Alameda Health System:

a. Agrees to abide by specific statutory requirements and prohibitions.
b. May access 340B drugs.

340B Policy Statements

HGH develops and maintains policies and procedures to ensure compliance with the guidelines and regulations of the 340B Drug Pricing Program for outpatients as outlined by Health Resources and Services Administration (HRSA)/Office of Pharmacy Affairs (OPA).

It is the policy of HGH to participate in the 340B Program, to comply with all rules and regulations of the 340B Program, and to implement procedures and safeguards to protect the integrity of the 340B Program including but not limited to the prevention of Duplicate Discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity, as well as adherence to the 340B Eligible Patient criteria.

The 340B Program savings will support HGH's mission to serve all and stretch federal resources and by providing more comprehensive services to patients.

HGH maintains auditable records demonstrating compliance with the 340B Program. These reports are reviewed by HGH biannually as part of its 340B Oversight Committee and compliance program.

Scope:

This policy applies to the 340B Programs Covered Entities/Child Sites identified below. All employees, contract employees, or agents providing services under 340B Program at HGH or a child site must adhere to this policy.

a. DSH050320: Alameda Health System – Highland General Hospital
b. DSH050320A: Alameda Health System –JGP Emergency PES (Psych Emergency Services)

Procedure:

I. Eligibility:

HGH ensures that 340B drugs are dispensed/administrated/prescribed only to eligible patients. HGH will also ensure that the following 340B eligibility determination filters are implemented:

1. Validates site eligibility. Care site must be within the four walls of the covered entity or listed as a child site on the HRSA OPAIS database as the point of service.
2. Determines patient status at the point of service.
   a. Patient must be in outpatient status at the time the medication is dispensed or administered based on medication type received.
3. HGH must maintain records of individual's health care. If the patient only receives prescriptions from the pharmacy, the patient is not considered as 340B eligible.
4. HGH deems patient care delivered via telehealth to constitute the provision of health care services by a health care professional that has a documented arrangement with HGH such that responsibility for care provided remains with HGH.
5. HGH must determine provider eligibility.
   a. Provider is either employed by the covered entity or provider health care on a contractual or other arrangement (e.g., referral for consultation), or granted privileges by covered entities.

b. Pharmacists and dieticians who are employed by Alameda Health System, practicing under a collaborative practice agreement within a clinic, may at times prescribe medications.

6. Ambulatory pharmacists, retail pharmacy pharmacists and dieticians are considered eligible providers under these terms. Encounter/prescription eligibility for Disease State management and/or MTM:
    a. The responsibility for the health care service that result in the use of, or prescription for, 340B drugs must remain with covered entity.
    b. Prescriptions will be deemed eligible if they meet one of the following criteria:
    c. A prescription is derived from a qualifying outpatient health care service documented within the previous 36 months from the date of fill.
    d. A qualifying outpatient health care service occurs within 30 days after the date of fill where the prescription is documented in the service summary.
7. HGH determines patients' Medicaid status at the point of service to prevent duplicate discounts. [1]
    a. GPO prohibition – Highland Hospital and child site John George Hospital are registered on the OPAIS 340B database as participating in the 340B Program are subject to the GPO prohibition and cannot obtain covered outpatient drugs through a GPO or other group purchasing arrangement.
    b. HGH may not purchase covered outpatient drugs through a GPO for any of its clinics/departments within the four walls of the hospital at any point in time. If HGH is unable to purchase a covered outpatient drug at the 340B price, written notification should be sent to OPA immediately.

    c. HGH will purchase using a non-GPO account and only replenish with 340B drugs once 340B patient eligibility is confirmed and can be documented through auditable records. Monthly audits are completed to ensure program integrity and report any violations.

II. II. Definitions:

1. 340B Eligible Patient – An individual is considered a "340B Eligible Patient" only if:
    a. HGH has an established relationship with the individual such that HGH maintains records of the individual's health care; and,
    b. The individual receives health care services from a health care professional who is either employed by HGH or who provides health care under contractual or other arrangements (e.g., referral or consultation) such that the responsibility for the individual's care remains with HGH. If health care is provided under referral for consultation, HRSA-recommended documentation is accessible:
        i. Request for referral

[1] Statutory Prohibition on Group Purchasing Organization Participation, *340B Drug Pricing Program Notice. Release No. 2013-1*; (February 3rd,2013). Health Resources and Services Administration Healthcare System Bureau Office of Pharmacy Affairs.
https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf

c. The entity maintains responsibility for the patient's health care services
d. An individual shall not be considered an "340B Eligible Patient" if the only health care service received by the individual from HGH is the dispensing of a drug or drugs for subsequent self-administration in a home setting or other institutional settings.
    - ***Referral Exception****: Though not a common practice, prescriptions written outside the Hospital may be filled with 340B drugs if they are written pursuant to a referral and (1) the referral and outcome of the referral are documented in the patient's medical record or (2) the patient obtained subsequent services from the Hospital for the same condition after the referral.*
e. The window for establishing 340B eligibility through care provided by Highland Hospital is based on a 36 month look back period form the date the prescription is filled.
f. Eligible encounter: Any encounter that support a continuing patient-provider relationship may include, but are not limited to office visit, telehealth appointments, refill requests, lab orders, imaging requests, and medication management consults. Any documented interaction that reasonably demonstrates the patient remains under the ongoing care of Highland Hospital maybe considered valid to support 340B eligibility.

2. Covered Drug–HGH does not purchase covered outpatient drugs for its outpatient registered facilities using a Group Purchasing Organization (GPO)
    a. HGH interprets the definition of covered outpatient drugs to include – 'An FDA-approved prescription drug, an over the counter (OTC) drug that is written on a prescription and a biological product that can be dispensed only by a prescription (other than a vaccine) or FDA-approved insulin.
    b. The following drugs and drug categories are excluded from 340B and are GPO exclusion exempt: vaccines, normal saline & water for injection, gases, contrast media/diagnostic agents, large volume fluids without additives, topicals, romiplostim, hyaluronan and hyaluronate derivatives, 503B purchased drugs, cellulose oxidized, state supplied emergency medication (e.g., Covid medications under emergency use approval) manufacturers/labelers that do not participate in 340B program, and bundled items. A detailed list of items and categories can be available through EHR.
    c. Controlled Substance Ordering System (CSOS): HGH is enrolled in the CSOS program which allows for secure electronic transmission of controlled substance orders without the paper DEA 222 Form. All pharmacists are enrolled with DEA to acquire a CSOS digital signing certificate in order to place control substance orders.

3. Covered Entity – covered entities include six categories of hospitals: disproportionate share hospitals (DSHs), children's hospitals, and cancer hospitals exempt from the Medicare perspective payment system, sole community hospitals, rural referral centers, and critical access hospitals (CAHs). Hospitals in each of these categories must be (1) non-profit, (2) be owned and operated by or under contract with state or local governments, and (3) except for CAHs, meet the payer-mix criteria related to the Medicare DSH program. [2]

[2] (Safety Net Hospitals for Pharmaceutical Access (SNPHA). "An Overview of The Section 340B Drug Discount Program.www.safetynetrx.org,2012)

4. Diversion – Pursuant to the 340B Program rules and regulations, 340B participating entities are prohibited from reselling or otherwise transferring outpatient drugs purchased at the statutory discount to an individual who is not a 340B Eligible Patient of HGH. Any such practice qualifies as "Diversion."

5. Duplicate Discount – A "Duplicate Discount," which is prohibited by the 340B statute, occurs when manufacturers provide both a 340B discount on a drug and pay a Medicaid rebate to the State on the same drug.

Contract Pharmacy Operations: [3]

HGH uses contract pharmacy services in accordance with HRSA requirements and guidelines.

HGH has obtained sufficient information from the contract pharmacy contractor to ensure compliance with applicable policy and legal requirements.

1. HGH registers each contract pharmacy location on the HRSA 340B Database prior to the use of 340B drugs at that site.
2. HGH uses a replenishment model using an 11-digit to 11-digit NDC match.
    a. Non-replenishment 340B inventory is never stored at the contract pharmacies, as all 340B stock is supplied through the replenishment model.
3. 340B-eligible prescriptions are presented to contract pharmacies via e-prescribing, hard copy, fax, or phone
    a. HGH Pharmacy staff verify patient, prescriber, and outpatient clinic eligibility via the electronic health record system.
    b. Updates are made to this mechanism by the HGH staff annually or on demand based on patient, provider, or contract pharmacy requests.
4. Contract Pharmacies dispense prescriptions to 340B eligible patients using non-340B drugs.
5. HGH implements bill-to, ship-to arrangement with the contract pharmacies.
    a. Contract Pharmacies order 340B drugs on behalf of HGH, based on eligible accumulation, as determined by HGH staff, through the drug wholesaler.
        i. Orders are triggered by the usage of package size of covered drugs determined by 11-digit NDC.
        ii. Replenishment orders through the wholesaler.
        iii. The wholesaler notifies HGH staff of medication shipped to contract pharmacies.
6. Contract Pharmacies receive 340B drug shipments. Orders are received by authorized pharmacy staff at the contract pharmacies.
7. Contract Pharmacy staff verify quantity received with the quantity ordered.
    a. Identifies inaccuracies.
    b. Resolves inaccuracies with the wholesaler.
    c. Document resolution of inaccuracies.
8. Contract Pharmacies notify HGH if they do not receive 11-digit NDC replenishment order within 90 days (about 3 months) or original order fulfillment request.
9. HGH reimburses contract pharmacies at a pre-negotiated rate per fill for such drugs.

10. HGH can review the invoice for drugs shipped to its contract pharmacies on demand.
11. HGH pays the invoice to wholesaler for all 340B drugs.
12. Contract Pharmacies provider HGH access to all pertinent reimbursement accounts and dispensing records. HGH staff retrieve and review 340B purchases every month.
13. Contract Pharmacies adjust claims when variance or discrepancy has occurred.
    a. Contract Pharmacies uses approved method regarding reconciliation between inventory and invoices with adjustment as necessary to match NDC or cost changes.
    b. Claim adjustments may occur only within 30 days of original billing and not without prior notice and approval of HGH.
14. Contract Pharmacies will not use 340B drugs for Medicaid patients (carve-out):
    a. Contract pharmacies will only dispense 340B drugs to patients who are eligible per HGH Electronic Health Record.
    b. Highland Hospital does not count 340B drug accumulation for Medicaid patients and therefore prevent(s) duplicate discounts for outpatient prescriptions.
15. HGH will audit all adjudicated claims at the contract pharmacies monthly and communicate any errors or inaccuracies to contract pharmacy staff within 5 business days of findings.
16. Independent external audits will be conducted annually to ensure program integrity. All audit results will be communicated to HGH within 90 days from the date of the audit.
    a. HGH will document and make corrections based on audit findings.
    b. All progress made will be documented and communicated to key stakeholders at the 340B Oversight Committee.

III. Responsibilities

This section includes stakeholders and determines their roles and responsibilities in maintaining 340B program integrity and compliance. The following staff members are key stakeholders in the 340B program, including governance and compliance, and should be standing members of the 340B Oversight Committee. HGH will identify who serves as the entity's authorizing official and primary contact for the 340B Program. These individuals are the sponsors of the 340B Oversight Committees.

1. Chief Financial Officer and/or VP of Finance
    a. Must account for savings and use of funds to provide care for the indigent under the indigent care agreement.
    b. Responsible for communication of all changes to the Medicare Cost report regarding clinics or revenue centers of the cost report.
    c. Responsible for communication of all changes to Medi-Cal/Medi-Cal Managed Care reimbursement for pharmacy services/products that impact 340B status (i.e., 340B AAC, modifiers).
    d. Accountable for savings and use of funds to provide care for the indigent under the indigent care agreement.

2. Chief Operations Officer (COO)

a. Responsible for attesting to the compliance of the program in the form of recertification.
b. Responsible as the principal officer in charge of the compliance and administration of the program.
c. Accountable agent for 340B compliance.
d. Responsible as the Authorizing Official for the 340B program.

3. System Director of Pharmacy
   a. Agent of the COO responsible to administer the 340B program to fully implement and optimize appropriate savings and ensure current policy statements and procedures are in place to maintain program compliance.
   b. Must maintain knowledge of the policy changes that impact the 340B program which includes, but is not limited to, HRSA/OPA rules and Medicaid changes
   c. Must coordinate constant knowledge of any change in clinic eligibility/information
   d. Responsible as the primary contact for the 340B program.

4. System 340B Manager
   b. Day to day management of the 340B program.
   d. Responsible for documentation of policies and procedures.
   g. Ensures appropriate safeguards and system integrity.
   h. Ensure compliance with 340B program requirements for qualified patients, drugs, providers, vendors, payers, and locations.
   i. Review and refine 340B cost saving report, detailing purchasing, and replacement practices, as well as dispensing patterns.
   j. Monitors ordering processes, integrating most current pricing from wholesalers, and analyzes invoices, shipping, and inventory processes.
   k. Design and maintain an internal audit plan of the compliance of the 340B program.
   l. Responsible for annual or semiannual physical inventory of pharmacy items.
   m. Designs the annual plan to cover all changes in the 340B program from the preceding year.

5. VP of Compliance and Internal Audit
   a. Design and maintain an internal audit plan of the compliance of the 340B program.

   b. Designs the annual plan to cover all changes in the 340B program from the preceding year.

6. Director of Finance/ Reimbursement
   a. Responsible for communication of all changes to the Medicare Cost Report regarding clinics or revenue centers.
   b. Responsible for communication of all changes to Medicaid reimbursement for pharmacy services/products that affect 340B status.
   c. Engage pharmacy in conversations that affect reimbursement.
   d. Responsible for modeling all managed care contracts (with/without 340B).

7. Revenue Cycle (Billing and Revenue Integrity) and Revenue IS:

a. Correct any findings identified through internal self-audits, independent external audits, or other methods.
b. IS team will conduct systematic correction in the electronic operating system.
c. IS team defines process and access to data for compliant identification of outpatient utilization for eligible patients.
d. Achieves the data to make them available to auditors when audited.

8. Office of the General Counsel ("OGC")

The OGC will provide legal counsel on an as-needed basis.

9. Pharmacy Buyer

Responsible for maintaining three distribution accounts, i.e., non-GPO account, 340B account, and GPO account. Responsible for maintaining direct accounts for GPO ("own use") class of trade as well as direct 340B accounts.

a. Responsible for ordering all medications from the specific accounts as appropriate.
b. Manage purchasing, receiving and inventory control processes.
c. Responsible for segregation, removal, and/or return of 340B drugs, including reverse distributor transactions.
d. Continuously monitor product min/max levels to effectively balance product availability and cost-efficient inventory control
e. Manage purchasing, receiving and inventory control processes.
f. Coordinate annual inventory cycle counts.
g. Monitor ordering processes, integrating most current pricing from wholesaler, analyze invoices, shipping, and inventory processes.

10. System 340B Analyst

a. Defines process and access to data for compliant identification of outpatient utilization for eligible patients.
c. Archives the data to make them available to auditors when audited.
d. Responsible for maintenance and testing of 340B management software.
e. In conjunction with any split-billing software vendor, develop and implement standard data interface controls which, at a minimum, shall perform necessary and reasonable checksum and duplicate record verifications.

IV. Program Integrity Procedures

1. As a participant in the 340B Drug Pricing Program, HGH shall meet all 340B Program eligibility requirements.

2. HGH OPA Database covered entity listing is complete, accurate, and correct.
   a. HGH, a member of AHS (Alameda Health System), a public Hospital Authority organized and existing under the laws of the State of California, provides health care services to low-income individuals.

i. For the most recent cost reporting period that ended before the calendar quarter involved, HGH had a disproportionate share adjustment percentage greater than or equal to 11.75 percent.

1. Reference Medicare Cost Report -Worksheet E Part A, line 33

3. HGH complies with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity. [REFERENCE: Public Law 102-585, Section 602, 340B Guidelines, 340B Policy Releases]
    a. HGH maintains auditable records demonstrating compliance with the 340B requirement
    b. Prescriber has participated in credentialing process therefore obtaining prescribing privileges and agrees to the rules and regulations established by HGH Medical Staff and is under contractual or other arrangements with the entity, and the patient receives a health care service from this professional such that the responsibility for care remains with the entity.
        i. The eligible prescriber listing is managed using credentialing software maintained by the Medical Staff Office & Credentialing and information from this database is imported into the HGH electronic health record system
    c. 340B drugs are used in outpatient facilities that appear as reimbursable on the most recently filed CMS cost report.
    d. Hospitals maintain records of the individual's health care.
    e. Patient is an outpatient at the time medication is administered or dispensed.
    f. HGH has systems/mechanisms and internal controls in place to ensure ongoing compliance with all 340B requirements.
    g. HGH has mechanisms in place to prevent diversion (see V. 340B Procurement, Inventory Management and Dispensing)
    h. HGH has mechanisms in place to prevent duplicate discounts (see VI. Safeguards to Prevent Duplicate Discounts). "UD" modifier and "08" modifier components will be audited quarterly internally. Any discrepancies will be communicated to the appropriate team for correction and resubmission. Discrepancies above self-disclosure thresholds will be reported based on self-disclosure guidelines.
    i. HGH has an internal audit plan and conducted quarterly (see Section VII).
    j. HGH may use contract pharmacy services (if applicable), and the contract pharmacy arrangement is performed in accordance with OPA requirements and guidelines.
4. HGH obtains sufficient information from the contract pharmacy to ensure compliance with applicable policy and legal requirements, and HGH has utilized an appropriate methodology to ensure compliance.
5. HGH has identified locations where it dispenses or prescribes 340B drugs:
    a. Within the four walls of the parent entity.
    b. With off-site outpatient locations that are fully integrated into the hospital, reimbursable on the most recently filed Medicare Cost Report, and registered on 340B OPAIS; and
    c. HGH owned and operated in house outpatient pharmacy.

6. Signed Contract Pharmacy Services Agreement(s) complies with the contract pharmacy essential compliance elements (https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf)

7. Material Breach:

A breach of 340B compliance requirements includes any adverse event that results in diversion and/or duplicate discounts.
The material breach threshold is defined as:

a. A violation(s) that exceed 5% of hospital 340B purchases, program savings, or impact to any manufacturer, and
b. Remains non-correctable within 30 days.

HGH acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any change in 340B eligibility or material breach by the hospital of any of the foregoing policies.

Violations identified through internal self-audits, independent external audits, or other methods that exceed the 5% threshold and remain non-correctable within the entity -defined period timeframe of review, will be immediately reported to HRSA and applicable manufacturers.

HGH elects to receive information about the 340B Program from trusted sources, including, but not limited to:

i. The Office of Pharmacy Affairs;
ii. The 340B Prime Vendor Program, managed by Apexus;
iii. Any OPA contractors.

8. 340B Program Education and Competency:

Program integrity and compliance are the responsibility of all 340B key stakeholders. Ongoing education and training are needed to ensure that these 340B key stakeholders have the knowledge to guarantee compliant 340B operations.

1. Alameda Health System Compliance department determines the knowledge and educational requirements for each 340B Program role (refer to "Responsibilities" section of this policy)
2. 340B key stakeholders complete initial basic training upon hire.
    a. Watch "introduction to the 340B Drug Pricing Program" on PVP website.
    b. Complete OnDemand modules on the PVP website.
3. 340B key stakeholders complete additional training as identified and pertaining to their responsibilities.
4. HGH provides educational updates and training, as needed to all staff.
5. HGH conducts annual verification of 340B program competency.
6. Training and education records are maintained per organizational policy and available for review.

9. 340B Enrollment, Recertification, Change Requests:

1. OPA requires entities to recertify their information as listed in the OPA database annually. HGH's Authorizing Official annually recertifies HGH's information by following the directions in the recertification email sent from the OPA to HGH's Authorizing Official by the requested deadline. Specific recertification questions will be sent to: 340b.recertification@hrsa.gov
2. HGH has available the requirement documents:
   a. Medicare Cost Report:
   i. Worksheet S, S-2, S-3
   ii. Worksheet E, Part. A
   iii. For outpatient facilities:
      a) Worksheet C
      b) Worksheet A
      c) Working trial balance.

b. Certification of ownership status.

3. On an annual basis, review Medicare Cost Report and confirm program status as outpatient

4. On a quarterly basis, review Medicaid Exclusion File for accuracy as a curve in the program

5. On a quarterly basis, review OPA 340b-database to confirm or revise listed NPI (National Provider Identifier) numbers

6. Enrollment Procedure: New Clinic Sites:
   a. The HGH Director of Pharmacy evaluates a new service area or facility to determine if the location is eligible for participation in the 340B Program. The criteria used include service area must be fully integrated into DSH, appear as a reimbursable clinic on the most recently filed cost report, have outpatient drug use, and care for patients that meet the 340B patient definition.

   b. If a new clinic meets these criteria, the Director of Pharmacy under the guidance of the Authorizing Official completes the online registration process during the registration window:
      - January 1–January 15 for an effective start date of April 1
      - April 1– April 15 for an effective start date of July 1
      - July 1–July 15 for an effective start date of October 1
      - October 1– October 15 for an effective start date of January 1

   This includes submitting cost report information, as required by OPA.
   http://www.hrsa.gov/opa/eligibilityandregistration/index.html

7. Changes to the Hospital's Information in the OPA Database:

It is HGH's ongoing responsibility to inform OPA of any changes to its information or eligibility. As soon as HGH is aware of its eligibility change, it will notify OPA immediately and stop purchasing of the 340B drugs as soon as HGH files its cost report with a disproportional share percentage < 11.75%. Change form will be submitted to OPA as soon as HGH is aware of the need to make a change to its database entry. HGH will expect changes to be reflected within 2 weeks of submission of the changes/requests.

V.340B Procurement, Inventory Management and Dispensing

340B inventory is procured and managed in the following settings:

1. **Highland Hospital Outpatient Retail Pharmacy**
    a. Prescription eligibility – HGH uses a physical inventory model for its outpatient retail pharmacy operations. The in-house pharmacy is closed door (processing only prescriptions that meet eligibility) and identifies as a Medicaid "carve-in" operation. Patient eligibility status is confirmed using one of the following mechanisms:
        i. Receipt of an electronic prescription from the hospital electronic health record
        ii. Receipt of a faxed prescription
        iii. Receipt of telephone orders which are reduced to writing
        iv. Receipt of a paper prescription that is either electronically generated from the hospital electronic health record or written by an eligible provider. If applicable, the paper prescription form will contain the appropriate watermarks and barcodes associated with either EHR (Electronic Health Record) generated prescriptions or those security requirements by CA Board of Pharmacy and Department of Justice Office of the Attorney General
    b. Medication replenishment - HGH Staff places orders from Wholesaler through daily inventory reviews and shelf inspections of PAR levels.
    c. Medication Storage – Upon receipt of inventory, HGH Staff examine the wholesaler invoice against the order, and reports inaccuracies to the wholesaler.
    d. Records - HGH Staff maintains records of 340B related transactions in accordance with California State Board of Pharmacy Rules and Regulations.
    e. Security - All inventories are stored in the pharmacy. Only pharmacy employees have access to the pharmacy using proximity badges.
    f. HGH Staff (and/or external vendor) conduct an annual physical inventory.

2. **Facility Administered Medications (Mixed Use Areas):**

a. HGH uses a 340B-replenishment inventory within the mixed encounter settings of the facility.

b. Inventory of medications in the mixed encounter setting is maintained using virtual inventory rather than maintenance of physical segregation. Virtual inventory requires initial purchase of unique 11-digit NDCs at a non-340B/non-GPO acquisition cost. As inventory is consumed, discrete units of the depleted inventory are tracked to ascertain whether the inventory was dispensed to outpatients (340B eligible) or inpatients (not eligible for 340B).

c. HGH Staff places inventory replenishment orders from Wholesaler through daily inventory reviews and shelf inspections

d. HGH Staff checks in inventory by examining the wholesaler invoice against the order, and reports inaccuracies to the wholesaler.

e. HGH Staff maintains auditable records of 340B related transactions in accordance with the California State board of Pharmacy Rules and Regulations.

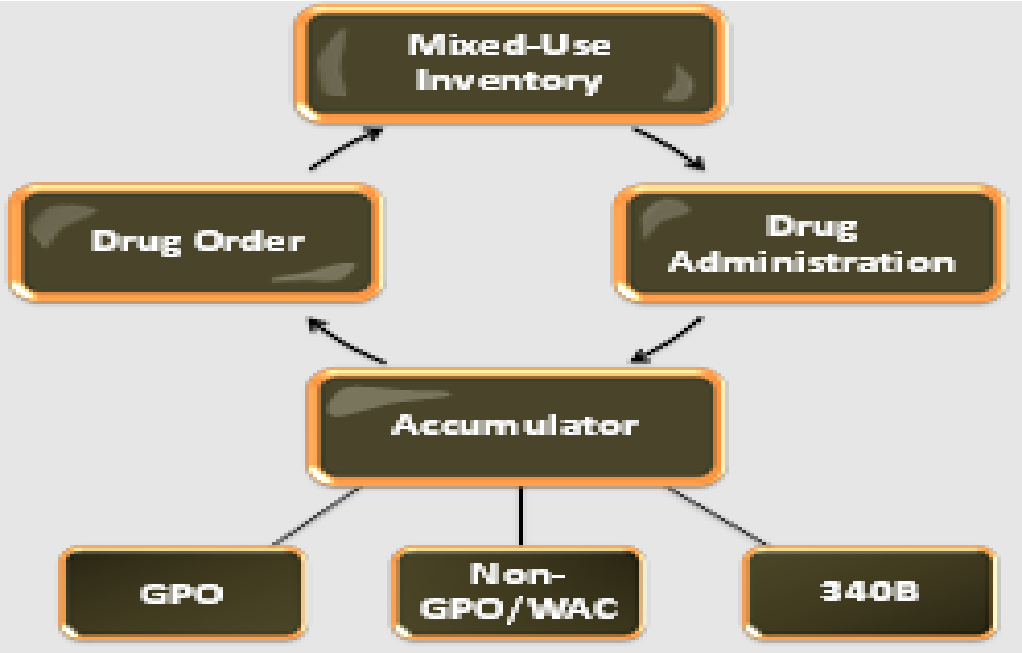
f. All inventory is stored either in the pharmacy maintained with a security system or in the ADS machines throughout the inpatient hospital and outpatient areas. Only pharmacy employees have access to the pharmacy using proximity badges. Only approved personnel have access to the ADS using fingerprint identification.

g. Mixed-use inventory replenishment is monitored by using split-billing software. Key points to address appropriate access to wholesaler accounts and split billing software include:

    a. HGH identifies all pharmacy purchasing accounts.
    b. HGH identifies which accounts are used for each 340B eligible location to purchase 340B drugs
    c. HGH places 340B, GPO, and WAC drug orders, based on orders created from the split-billing system.
        a. 340B drugs are ordered at an 11-digit NDC level.
        b. Appropriate processes are in place to ensure proper ordering, tracking, and adjusting of accumulators for controlled substances
    d. HGH receives shipments.
    e. HGH verifies quantity received with the quantity ordered.
        a. Identifies inaccuracies.
        b. Resolves inaccuracies
        c. Documents resolution of inaccuracies
    f. HGH documents manual manipulations to the 340B split-billing accumulator, including reason for manual manipulations.
    g. HGH reviews purchasing records with dispensing records biannually to ensure that covered outpatient drugs purchased through the 340B program are used only for 340B eligible patients.
    h. HGH staff reports significant discrepancies to HGH management within one business day.
    i. HGH maintains records of 340B – related transactions for a period of 3 years in a readily retrievable format.
        a. These reports are reviewed by Highland Hospital as part of its 340B oversight and compliance program.
    j. The infusion center data tracked by split-billing software is not used for inventory tracking purposes. Data is used only as a secondary reference tool.

h. Wasted/Expired 340B medication:
    a. HGH pharmacy staff documents destroyed or wasted drugs.
    b. System 340B analyst adjust the 340B accumulators based on reported waste.

i. HGH Staff (and/or external vendor) conduct an annual physical inventory.



0. Purchase mixed-use inventory (according to eligible accumulations).
1. Administered and dispensed drugs to patients.
2. Accumulator accumulates drug on an 11-digit NDC match until the unit of use is met, prepares order, uses patient/clinic/prescriber information to determine the appropriate contract for ordering.

GPO	Non-GPO (Non-340B WAC)	340B
GPO/Inpatient class of trade: Inpatient status determined by the hospital at the date/time of administration GPO/Outpatient class of trade: Offsite/unregistered outpatient clinics	Products that do not have an 11-digit NDC match on the 340B contract but are otherwise eligible for 340B purchase Non-340B eligible outpatients, i.e.: Administration or dispensing occurred at a clinic within 4 walls of covered entity, but not 340B eligible Medicaid carve-out outpatients Lost charges or wasted product	Patients met 340B patient definition and received services on an outpatient basis in a 340B registered/participating hospital clinic

- Replenishment drug order(s) are placed according to eligible accumulations.

3.Outpatient Clinic Administered Medications (Highland Wellness Center Clinics)

a. HGH uses 340B medications in all the outpatient ambulatory care clinics.

b. All medications ordered for immediate administration must be documented in the EHR (Electronic Health Record) or medical record

c. Most medications are stored in ADS Machines located in the clinic. Any unavailable medications prescribed for immediate administration must be requested via a patient-specific requisition form and brought to the main K-3 Pharmacy for filling and charging through the EHR.

d. If there are no ADS available, approved medications can be requested through a requisition form, and securely stored in the medication area of the clinic. When administered, these medications must be documented using the EHR to include administration date, patient identifiers and the medication administered.

e. Medication replenishment - HGH Staff places orders from Wholesaler through daily inventory reviews and shelf inspections of PAR levels daily.

f. Medication Storage – Upon receipt of inventory, HGH Staff examines the wholesaler invoice against the order, and reports inaccuracies to the wholesaler.

g. Records - HGH Staff maintains records of 340B related transactions in accordance with California State Board of Pharmacy Rules and Regulations.

h. All inventory is stored either in the pharmacy maintained with a security system or in the ADS machines throughout outpatient clinics. Only pharmacy employees have access to the pharmacy using proximity badges needed to access the department. Only approved personnel have access to the ADS using fingerprint identification.

i. All patients treated in the outpatient infusion center meet the criteria for 340B eligibility. Inventory of medications for the Outpatient Infusion Center is physically segregated from all other medications in the pharmacy and is purchased on a separate and dedicated 340B account. Drug utilization data for these patients will not accumulate on our “virtual inventory” management system.

j. HGH Staff (and/or external vendor) conducts an annual physical inventory.

3. Drug Shortage/340B Price not available

a. Highland Hospital will purchase covered outpatient drugs at 340B price. During times of Drug Shortages or when 340B price is not available, HGH will contact the drug manufacturer.
b. Covered outpatient drug will be purchased on a non-GPO account if the 340B price is not available. If the drug cannot be purchased on a non-GPO account, HGH may use GPO

alternative only if Highland Hospital documents and maintains records that all other options have been exhausted.

c. Highland Hospital must attempt to purchase drug at 340B price every time an order is made.

4. Contract Pharmacy:

a. Separate 340B and non-340B purchased inventory is used for Contract Pharmacies.
b. Pharmacy staff dispense 340B drugs only to patients meeting all the criteria in the "Patient Eligibility/Definition" policy.

Inventory Replenishment system (340B/non-340B) is maintained at Contract Pharmacies.

1. Highland Hospital Pharmacy staff identifies all accounts used for purchasing drugs at contract pharmacies for 340B and non-340B

1. Highland Hospital purchases inventory according to eligible accumulations recorded for 340B replenishment at contract pharmacies.
2. Contract Pharmacies dispense drugs to patients.
3. HGH staff track drug utilizations based on patient eligibility including service location and provider information. This accumulation occurs at the 11-digit NDC level and a full package size will be accumulated before replenishing inventory.

VI.. Safeguards to Prevent Duplicate Discounts

a. HGH is a CA Medi-Cal "Carve in" facility and bills Medicaid per reimbursement requirements, and as reflected its information on the OPA website as Carve in. HGH bills Medicaid per Medi-Cal reimbursement requirements, and as such HGH has reflected its information on the OPA website/Medicaid Exclusion (http://opanet.hrsa.gov/340B/Views/CoveredEntity/SearchDirectory)
    a. HGH informs OPA immediately of any changes to its information on the OPA website/Medicaid Exclusion File
        i. HGH is responsible for the accuracy of the information in Medicaid Exclusion File (MEF) The MEF (Medicaid Exclusion File) lists covered entities that have decided to use 340B drugs for their Medicaid patients and to bill Medicaid for those drugs (carve-in). Having this information in the MEF (Medicaid Exclusion File) indicates to the states and manufacturers which drugs are not subject to Medicaid rebates, and helps ensure the prevention of duplicate discounts, as prohibited by statute.
        ii. Covered entities are required to ensure that information in the MEF is accurate each quarter and at the time of annual recertification.

b. To identify 340B-eligible claims submitted to Medicaid by the Highland Hospital Outpatient Pharmacy, the MISC 1/MSC 1 field has the qualifier titled "08 – 340B/Share Pricing/Public Health".
c. Highland Hospital does not in the course of regular business bill Out of State Medicaid and Managed Medicaid for 340B drugs in the hospital mixed-use and retail pharmacy.

d. A UD Modifier is used for physician-administered claims to identify a 340B purchased drug by using the reporting modifier "UD" in conjunction with the procedures code on the state or federal billing form. When a claim is filed with Medicaid for administering drugs purchased under the 340B drug discount program, a modifier "UD" along with the 11-digit National Drug Code (NDC).
e. John George Psychiatric Hospital, child site, does not bill Medi-Cal and is paid at an hourly/per diem rate for all patient care services by the County of Alameda.

VII.. Emergency and Disaster Medication

Bioterrorism/ FEMA process:

HGH has an agreement with FEMA, Oakland Urban Search and Rescue Task Force (US&R TF), and Alameda County to supply (sell) certain medications during a declared emergency. The purpose of emergency medication is to respond to a disaster in the United States, which overwhelms the resources of local or state authorities. The Emergency medications will not be used for HGH's patients. All emergency meds are physically separated from the mixed-use inventory and purchased on GPO exclusively upon disaster activation.

Flexibility During Emergency:
In the event of a State of Emergency providers may work past term date if necessary due to hospital occupancy.

VIII. Loan/Borrow Processes:

The borrowing and lending process is evaluated based on different criteria, such as 340B status, emergent need, or inventory availability at each pharmacy. See policy: "Borrowing and Loaning Medications Between AHS Inpatient Pharmacies."

IX.. Monitoring and Reporting:

1. Monitoring
    a. The entity uses the process outlined in: 340B Compliance Self-Assessment: Self-Audit Process to Ensure 340B Compliance. Additional monitoring or reporting includes:
        i. Daily monitoring of accrual file upload to wholesaler
        ii. Ongoing monitoring of unreconciled dispenses and wastes
        iii. Ongoing collaboration with Pharmacy IT (Information Technology) to ensure products, units, quantities, prices are up-to-date and correctly represented.
    b. Review of outpatient retail pharmacy prescriptions to ensure eligibility

2. 340B Compliance Overview

a. The 340B Compliance Review summarizes all activities necessary to ensure comprehensive review of 340B compliance at HGH. HGH staff is responsible and accountable for overseeing this review process, as well as taking corrective actions based upon findings.

		Area of Focus			
Activity	Frequency	HGH Eligibility	No Diversion	No Duplicate Discount	GPO Prohibition
Review of all OPA database information for HGH, indigent care agreement with state/local government, and Medicare Cost Report (Worksheet E, Part A and Worksheet A), prior to recertification Internal Compliance *Staff responsible: Director of Pharmacy, System 340B Manager & CFO*	Annual	√			
Review of 340B Self-Audit Reports (mixed-use & outpatient pharmacy) *Staff responsible: System 340B Manager, Director of Pharmacy, CFO, COO*	Quarterly		√	√	√
Review of quarterly contract price load *Staff responsible: Director of Pharmacy, System 340B Manager, System 340B Analyst*	Quarterly		√		
Update of prescriber eligibility files with outpatient patient management processing system *Staff responsible: Provider Service Director and EHR IT manager, system 340B manager*	Monthly		√		
Split-Billing software maintenance (CDM-NDC mapping, updates, etc.) *Staff responsible: System 340B Analyst, System 340B Manager*	Daily or Weekly		√		√

b. Quarterly internal audits will be performed by designated pharmacy staff and reviewed by the Director of Pharmacy. HGH staff are responsible and accountable for overseeing this review process, as well as taking corrective actions based upon findings.
i. Infusion Center audit:
Audits will include, but not limited to, ensuring the patient meets 340B eligibility, the medications were purchased from the 340B account specific for infusion center and that the medications are dispensed from our physically segregated inventory for the infusion center.
ii. Mixed- use area/hospital audits:

Audits will include, but not limited to, ensuring the patients meeting 340B eligibility, the charge on dispense data is accurate, patient status is outpatient, patient had an order for the medication and was written by an eligible provider and the medication accumulated in the correct account in our virtual inventory records.

2. Reporting Non-Compliance
    a. HGH acknowledges that if there is a breach of the 340B requirements, HGH may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and depending upon the circumstances, may be subject to the repayment of interest and/or removal from the list of eligible 340B entities.
    b. As HGH identifies areas/types of non-compliance related to entity eligibility, diversion, or duplicate discount, HGH will notify OPA, and any associated drug manufacturers complete with appropriate documentation/records along with a plan for corrective action.
    c. Threshold to self-report:
    Violations identified through internal self-audits, independent external audits, or other methods that exceed the 5% threshold and remain non-correctable within the entity - defined period timeframe of review, as defined as Material Breach under this Policy, will be immediately reported to HRSA and applicable manufacturers. The Self-Disclosure Tool included in this Policy may be utilized to assist Covered Entity in self-reporting a Material Breach.

References

1. Section 340B of the Public Health Service Act.
2. Apexus 340B University
3. Apexus 340B Tools https://www.apexus.com/solutions/education/340b-tools
4. HRSA Entity Self-Disclosures: https://www.hrsa.gov/opa/self-disclosures/self-disclosure.html
5. Apexus 340B Self disclosure tool: https://www.340bpvp.com/resource-center/340b-tools
6. Apexus 340B Material Breaching threshold: https://www.340bpvp.com/resource-center/340b-tools

APPROVALS

		System	AHS Core	Alameda
Compliance Dept.	**Date:**	**11/2021**		
Legal Dept.	**Date:**	**11/2021**		
Pharmacy Dept.	**Date:**	**6/2025**		
System P&T	**Date:**	**6/2025**		
Clinical Practice Committee	**Date:**	**7/2025**		

Medical Executive Committee	**Date:**	**7/2025**		
Board of Trustees	**Date:**	**8/2025**		

Alameda Hospital

A Member of Alameda Health System

340B DRUG PRICING PROGRAM (ALAMEDA HOSPITAL)

Department	AHD AHD PHARMACY, PHARMACY	***Effective Date***	2/2016
Campus	Alameda Hospital	***Date Revised***	9/2015, 6/2016, 8/2017, 12/2018, 7/2019, 12/2022, 6/2025
Unit	All	***Next Scheduled Review***	6//2028
Manual	Pharmacy	***Author***	Director, Pharmacy
Replaces the following Policies:		***Responsible Person***	Chief Operating Officer

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

Purpose

The purpose of this policy is to establish guidance regarding Alameda Hospital (AH) and all child sites' compliance with the rules and regulations set forth by the Health Resources and Services Administration's Office of Pharmacy Affairs ("OPA") pertaining to the Section 340B Drug Discount Program

Background

Section 340B of the Public Health Service Act (1992) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign a pharmaceutical pricing agreement (PPA) with the Secretary of Health and Human Services.

a. This agreement limits the price that manufacturers may charge certain covered entities for covered outpatient drugs.

The 340B Program is administered by the federal Health Resources and Services Administration (HRSA) in the Department of Health and Human Services (DHHS).

Upon registration on 340B OPAIS (Office of Pharmacy Affairs Information System), Alameda Health System:

a. Agrees to abide by specific statutory requirements and prohibitions.
b. May access 340B drugs.

340B Policy Statements

Alameda Hospital (AH) develops and maintains policies and procedures to ensure compliance with the guidelines and regulations of the 340B Drug Pricing Program for outpatients as outlined by Health Resources and Services Administration (HRSA)/Office of Pharmacy Affairs (OPA).

It is the policy of AH to participate in the 340B Program, to comply with all rules and regulations of the 340B Program, and to implement procedures and safeguards to protect the integrity of the 340B Program including but not limited to the prevention of Duplicate Discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity, as well as adherence to the 340B Eligible Patient criteria.

The 340B Program savings will support AH's mission to serve all and stretch federal resources and by providing more comprehensive services to patients.

AH maintains auditable records demonstrating compliance with the 340B Program. These reports are reviewed by AH biannually as part of its 340B Oversight Committee and compliance program.

Scope:

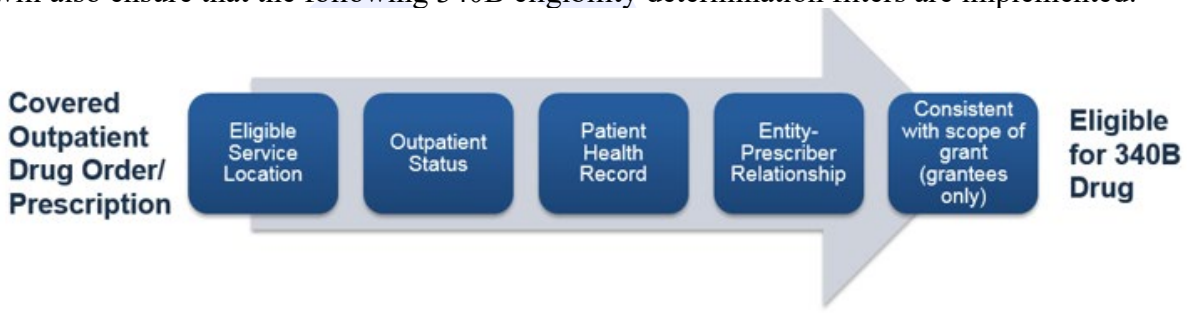
This policy applies to the 340B Programs Covered Entities/Child Sites identified below. All employees, contract employees, or agents providing services under the 340B Program at AH or a child site must adhere to this policy.

a. DSH050211: Alameda Health System –Alameda Hospital
b. DSH050211A: Alameda Health System –AH Wound Care Clinic

Procedure:

I. Eligibility:

AH ensures that 340B drugs are dispensed/administrated/prescribed only to eligible patients. AH will also ensure that the following 340B eligibility determination filters are implemented:



1. Validates site eligibility. Care site must be within the four walls of the covered entity or listed as a child site on the HRSA OPAIS database as the point of service.
2. Determines patient status at the point of service.
   a. Patient must be in outpatient status at the time the medication is dispensed or administered based on medication type received.
3. AH must maintain records of individual's health care. If the patient only receives prescriptions from the pharmacy, the patient is not considered as 340B eligible.

4. AH deems patient care delivered via telehealth to constitute the provision of health care services by a health care professional that has a documented arrangement with AH such that responsibility for care provided remains with AH.
5. AH must determine provider eligibility.
    a. Provider is either employed by the covered entity or provider health care on a contractual or other arrangement (e.g., referral for consultation) or granted privileges by covered entities.
    b. Pharmacists and dieticians who are employed by Alameda Health System, practicing under a collaborative practice agreement within a clinic, may at times prescribe medications.
        a. Ambulatory pharmacists and dieticians are considered eligible providers under these terms.

6. Encounter/prescription eligibility for Disease State management and/or MTM:
    a. The responsibility for the health care service that result in the use of, or prescription for, 340B drugs must remain with covered entity.
    b. Prescriptions will be deemed eligible if they meet one of the following criteria:
        a. A prescription is derived from a qualifying outpatient health care service documented within the previous 36 months from the date of fill.
        b. A qualifying outpatient health care service occurs within 30 days after the date of fill where the prescription is documented in the service summary.

7. AH determines patient's Medicaid status at the point of service to prevent duplicate discounts.[1]

    a. GPO prohibition – Alameda Hospital and child site AH Wound Care Clinics are registered on the OPAIS 340B database as participating in the 340B Program are subject to the GPO prohibition and cannot obtain covered outpatient drugs through a GPO or other group purchasing arrangement.
    b. AH may not purchase covered outpatient drugs through a GPO for any of its clinics/departments within the four walls of the hospital at any point in time. If AH is unable to purchase a covered outpatient drug at the 340B price, written notification should be sent to OPA immediately.

    c. AH will purchase using a non-GPO account and only replenish with 340B drugs once 340B patient eligibility is confirmed and can be documented through auditable records. Monthly audits are completed to ensure program integrity and report any violations.

II. <u>Definitions:</u>

1. 340B Eligible Patient – An individual is considered a "340B Eligible Patient" only if:

[1] Statutory Prohibition on Group Purchasing Organization Participation, *340B Drug Pricing Program Notice. Release No. 2013-1*; (February 3rd,2013). Health Resources and Services Administration Healthcare System Bureau Office of Pharmacy Affairs. https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf

a. AH has an established relationship with the individual such that AH maintains records of the individual's health care; and,
b. The individual receives health care services from a health care professional who is either employed by AH or who provides health care under contractual or other arrangements (e.g., referral or consultation) such that the responsibility for the individual's care remains with AH. If health care is provided under referral for consultation, HRSA-recommended documentation is accessible:
    i. Request for referral
c. The entity maintains responsibility for the patient's health care services
d. An individual shall not be considered an "340B Eligible Patient" if the only health care service received by the individual from AH is the dispensing of a drug or drugs for subsequent self-administration in a home setting or other institutional settings.
    - ***Referral Exception**: Though not a common practice, prescriptions written outside the Hospital may be filled with 340B drugs if they are written pursuant to a referral and (1) the referral and outcome of the referral are documented in the patient's medical record or (2) the patient obtained subsequent services from the Hospital for the same condition after the referral.*
e. The window for establishing 340B eligibility through care provided by Alameda Hospital is based on a 36 month look back period form the date the prescription is filled.
f. Eligible encounter: Any encounter that support a continuing patient-provider relationship may include, but are not limited to office visit, telehealth appointments, refill requests, lab orders, imaging requests, and medication management consults. Any documented interaction that reasonably demonstrates the patient remains under the ongoing care of Alameda Hospital maybe considered valid to support 340B eligibility.

2. Covered Drug–AH does not purchase covered outpatient drugs for its outpatient registered facilities using a Group Purchasing Organization (GPO)
    a. AH interprets the definition of covered outpatient drugs to include – 'An FDA-approved prescription drug, an over the counter (OTC) drug that is written on a prescription and a biological product that can be dispensed only by a prescription (other than a vaccine) or FDA-approved insulin.
    b. The following drugs and drug categories are excluded from 340B and are GPO exclusion exempt: vaccines, normal saline & water for injection, gases, contrast media/diagnostic agents, large volume fluids without additives, topicals, romiplostim, hyaluronan and hyaluronate derivatives, 503B purchased drugs, cellulose oxidized, state supplied emergency medication (e.g., Covid medications under emergency use approval) manufacturers/labelers that do not participate in 340B program, and bundled items. A detailed list of items and categories can be available through EHR.
    c. Controlled Substance Ordering System (CSOS): AH is enrolled in the CSOS program which allows for secure electronic transmission of controlled substance orders without the paper DEA 222 Form. Pharmacists are enrolled with DEA to acquire a CSOS digital signing certificate in order to place control substance orders.

3. Covered Entity – covered entities include six categories of hospitals: disproportionate share hospitals (DSHs), children's hospitals, and cancer hospitals exempt from the Medicare perspective payment system, sole community hospitals, rural referral centers, and critical access hospitals (CAHs). Hospitals in each of these categories must be (1) non-profit, (2) be owned and operated by or under contract with state or local governments, and (3) except for CAHs, meet the payer-mix criteria related to the Medicare DSH program. [2]

4. Diversion – Pursuant to the 340B Program rules and regulations, 340B participating entities are prohibited from reselling or otherwise transferring outpatient drugs purchased at the statutory discount to an individual who is not a 340B Eligible Patient of AH. Any such practice qualifies as "Diversion."

5. Duplicate Discount – A "Duplicate Discount," which is prohibited by the 340B statute, occurs when manufacturers provide both a 340B discount on a drug and pay a Medicaid rebate to the State on the same drug.

III. Responsibilities

This section includes stakeholders and determines their roles and responsibilities in maintaining 340B program integrity and compliance. The following staff members are key stakeholders in the 340B program, including governance and compliance, and should be standing members of the 340B Oversight Committee. AH will identify who serves as the entity's authorizing official and primary contact for the 340B Program. These individuals are the sponsors of the 340B Oversight Committees.

1. Chief Financial Officer and/or VP of Finance
    a. Must account for savings and use of funds to provide care for the indigent under the indigent care agreement.
    b. Responsible for communication of all changes to the Medicare Cost report regarding clinics or revenue centers of the cost report.
    c. Responsible for communication of all changes to Medi-Cal/Medi-Cal Managed Care reimbursement for pharmacy services/products that impact 340B status (i.e., 340B AAC, modifiers).
    d. Accountable for savings and use of funds to provide care for the indigent under the indigent care agreement.

2. Chief Operations Officer (COO)
    a. Responsible for attesting to the compliance of the program in the form of recertification.
    b. Responsible as the principal officer in charge of the compliance and administration of the program.
    c. Accountable agent for 340B compliance.

[2] (Safety Net Hospitals for Pharmaceutical Access (SNPHA). "An Overview of The Section 340B Drug Discount Program.www.safetynetrx.org,2012)

d. Responsible as the Authorizing Official for the 340B program.

3. Director of Pharmacy
   a. Agent of the COO responsible to administer the 340B program to fully implement and optimize appropriate savings and ensure current policy statements and procedures are in place to maintain program compliance.
   b. Must maintain knowledge of the policy changes that impact the 340B program which includes, but is not limited to, HRSA/OPA rules and Medicaid changes
   c. Must coordinate constant knowledge of any change in clinic eligibility/information

4. System 340B Manager
   b. Day to day management of the 340B program.
   d. Responsible for documentation of policies and procedures.
   g. Ensures appropriate safeguards and system integrity.
   h. Ensure compliance with 340B program requirements for qualified patients, drugs, providers, vendors, payers, and locations.
   i. Review and refine 340B cost saving report, detailing purchasing, and replacement practices, as well as dispensing patterns.
   j. Monitors ordering processes, integrating most current pricing from wholesalers, and analyzes invoices, shipping, and inventory processes.
   k. Design and maintain an internal audit plan of the compliance of the 340B program.
   l. Responsible for annual or semiannual physical inventory of pharmacy items.
   m. Designs the annual plan to cover all changes in the 340B program from the preceding year.
   n. Responsible as the primary contact for the 340B program.

5. VP of Compliance and Internal Audit
   a. Design and maintain an internal audit plan of the compliance of the 340B program.

   b. Designs the annual plan to cover all changes in the 340B program from the preceding year.

6. Director of Finance/ Reimbursement
   a. Responsible for communication of all changes to the Medicare Cost Report regarding clinics or revenue centers.
   b. Responsible for communication of all changes to Medicaid reimbursement for pharmacy services/products that affect 340B status.
   c. Engage pharmacy in conversations that affect reimbursement.
   d. Responsible for modeling all managed care contracts (with/without 340B).

7. Revenue Cycle (Billing and Revenue Integrity) and Revenue IS:
   a. Correct any findings identified through internal self-audits, independent external audits, or other methods.
   b. IS team will conduct systematic correction in the electronic operating system.

c. IS team defines process and access to data for compliant identification of outpatient utilization for eligible patients.
d. Achieves the data to make them available to auditors when audited.

8. Office of the General Counsel ("OGC")

The OGC will provide legal counsel on an as-needed basis.

9. Pharmacy Buyer

Responsible for maintaining three distribution accounts, i.e., non-GPO account, 340B account, and GPO account. Responsible for maintaining direct accounts for GPO ("own use") class of trade as well as direct 340B accounts.

a. Responsible for ordering all medications from the specific accounts as appropriate.
b. Manage purchasing, receiving and inventory control processes.
c. Responsible for segregation, removal, and/or return of 340B drugs, including reverse distributor transactions.
d. Continuously monitor product min/max levels to effectively balance product availability and cost-efficient inventory control
e. Manage purchasing, receiving and inventory control processes.
f. Coordinate annual inventory cycle counts.
g. Monitor ordering processes, integrating most current pricing from wholesaler, analyze invoices, shipping, and inventory processes.

10. IT Pharmacist

a. Defines process and access to data for compliant identification of outpatient utilization for eligible patients.
c. Archives the data to make them available to auditors when audited.
d. Responsible for maintenance and testing of 340B management software.
e. In conjunction with any split-billing software vendor, develop and implement standard data interface controls which, at a minimum, shall perform necessary and reasonable checksum and duplicate record verifications.

IV. Program Integrity Procedures

1. As a participant in the 340B Drug Pricing Program, AH shall meet all 340B Program eligibility requirements.

2. AH OPA Database covered entity listing is complete, accurate, and correct.
   a. AH, a member of AHS (Alameda Health System), a public Hospital Authority organized and existing under the laws of the State of California, provides health care services to low-income individuals.

      i. For the most recent cost reporting period that ended before the calendar quarter involved, AH had a disproportionate share adjustment percentage greater than or equal to 11.75 percent.

         1. Reference Medicare Cost Report -Worksheet E Part A, line 33

3. AH complies with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity. [REFERENCE: Public Law 102-585, Section 602, 340B Guidelines, 340B Policy Releases]
    a. AH maintains auditable records demonstrating compliance with the 340B requirement
    b. Prescriber has participated in credentialing process therefore obtaining prescribing privileges and agrees to the rules and regulations established by AH Medical Staff and is under contractual or other arrangements with the entity, and the patient receives a health care service from this professional such that the responsibility for care remains with the entity.
        i. The eligible prescriber listing is managed using credentialing software maintained by the Medical Staff Office & Credentialing and information from this database is imported into the AH electronic health record system
    c. 340B drugs are used in outpatient facilities that appear as reimbursable on the most recently filed CMS cost report.
    d. Hospitals maintain records of the individual's health care.
    e. Patient is an outpatient at the time medication is administered or dispensed.
    f. AH has systems/mechanisms and internal controls in place to ensure ongoing compliance with all 340B requirements.
    g. AH has mechanisms in place to prevent diversion (see V. 340B Procurement, Inventory Management and Dispensing)
    h. AH has mechanisms in place to prevent duplicate discounts (see VI. Safeguards to Prevent Duplicate Discounts). "UD" modifier components will be audited quarterly internally. Any discrepancies will be communicated to the appropriate team for correction and resubmission. Discrepancies above self-disclosure thresholds will be reported based on self-disclosure guidelines.
    i. AH has an internal audit plan and conducts quarterly (see Section VII).
4. AH has identified locations where it dispenses or prescribes 340B drugs:
    a. Within the four walls of the parent entity.
    b. With off-site outpatient locations that are fully integrated into the hospital, reimbursable on the most recently filed Medicare Cost Report, and registered on 340B OPAIS; and

5. Material Breach:

A breach of 340B compliance requirements includes any adverse event that results in diversion and/or duplicate discounts.
The material breach threshold is defined as:

a. A violation(s) that exceed 5% of hospital 340B purchases, program savings, or impact to any manufacturer, and
b. Remains non-correctable within 30 days.

AH acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any change in 340B eligibility or material breach by the hospital of any of the foregoing policies.

Violations identified through internal self-audits, independent external audits, or other methods that exceed the 5% threshold and remain non-correctable within the entity -defined period timeframe of review, will be immediately reported to HRSA and applicable manufacturers.

AH elects to receive information about the 340B Program from trusted sources, including, but not limited to:

i. The Office of Pharmacy Affairs;
ii. The 340B Prime Vendor Program, managed by Apexus;
iii. Any OPA contractors.

6. 340B Program Education and Competency:

Program integrity and compliance are the responsibility of all 340B key stakeholders. Ongoing education and training are needed to ensure that these 340B key stakeholders have the knowledge to guarantee compliant 340B operations.

1. Alameda Health System Compliance department determines the knowledge and educational requirements for each 340B Program role (refer to "Responsibilities" section of this policy)
2. 340B key stakeholders complete initial basic training upon hire.
    a. Watch "introduction to the 340B Drug Pricing Program" on PVP website.
    b. Complete OnDemand modules on the PVP website.
3. 340B key stakeholders complete additional training as identified and pertaining to their responsibilities.
4. AH provides educational updates and training, as needed to all staff.
5. AH conducts annual verification of 340B program competency.
6. Training and education records are maintained per organizational policy and available for review.

7. <u>340B Enrollment, Recertification, Change Requests:</u>

1. OPA requires entities to recertify their information as listed in the OPA database annually. AH's Authorizing Official annually recertifies AH's information by following the directions in the recertification email sent from the OPA to AH's Authorizing Official by the requested deadline. Specific recertification questions will be sent to: <u>340b.recertification@hrsa.gov</u>
2. AH has available the requirement documents:
    a. Medicare Cost Report:
    i. Worksheet S, S-2, S-3
    ii. Worksheet E, Part. A
    iii. For outpatient facilities:
        a) Worksheet C
        b) Worksheet A
        c) Working trial balance.

b. Certification of ownership status.

3. On an annual basis, review Medicare Cost Report and confirm program status as outpatient

4. On a quarterly basis, review Medicaid Exclusion File for accuracy as a curve in the program

5. On a quarterly basis, review OPA 340b-database to confirm or revise listed NPI (National Provider Identifier) numbers

6. Enrollment Procedure: New Clinic Sites:
    a. The AH Director of Pharmacy evaluates a new service area or facility to determine if the location is eligible for participation in the 340B Program. The criteria used include service area must be fully integrated into DSH, appear as a reimbursable clinic on the most recently filed cost report, have outpatient drug use, and care for patients that meet the 340B patient definition.

    b. If a new clinic meets these criteria, the Director of Pharmacy under the guidance of the Authorizing Official completes the online registration process during the registration window:
        - January 1–January 15 for an effective start date of April 1
        - April 1– April 15 for an effective start date of July 1
        - July 1–July 15 for an effective start date of October 1
        - October 1– October 15 for an effective start date of January 1

    This includes submitting cost report information, as required by OPA.
    http://www.hrsa.gov/opa/eligibilityandregistration/index.html

7. Changes to the Hospital's Information in the OPA Database:

It is AH's ongoing responsibility to inform OPA of any changes to its information or eligibility. As soon as AH is aware of its eligibility change, it will notify OPA immediately and stop purchasing of the 340B drugs as soon as AH files its cost report with a disproportional share percentage < 11.75%. Change form will be submitted to OPA as soon as AH is aware of the need to make a change to its database entry. AH will expect changes to be reflected within 2 weeks of submission of the changes/requests.

V.340B Procurement, Inventory Management and Dispensing

340B inventory is procured and managed in the following settings:

1. **Facility Administered Medications (Mixed Use Areas):**

a. AH uses a 340B-replenishment inventory within the mixed encounter settings of the facility.

b. Inventory of medications in the mixed encounter setting is maintained using virtual inventory rather than maintenance of physical segregation. Virtual inventory requires initial purchase of unique 11-digit NDCs at a non-340B/non-GPO acquisition cost. As inventory is consumed, discrete units of the depleted inventory are tracked to ascertain whether the inventory was dispensed to outpatients (340B eligible) or inpatients (not eligible for 340B).

c. AH Staff places inventory replenishment orders from Wholesaler through daily inventory reviews and shelf inspections

d. AH Staff checks in inventory by examining the wholesaler invoice against the order, and reports inaccuracies to the wholesaler.

e. AH Staff maintains auditable records of 340B related transactions in accordance with the California State board of Pharmacy Rules and Regulations.

f. All inventory is stored either in the pharmacy maintained with a security system or in the ADS machines throughout the inpatient hospital and outpatient areas. Only pharmacy employees have access to the pharmacy using proximity badges. Only approved personnel have access to the ADS using fingerprint identification.

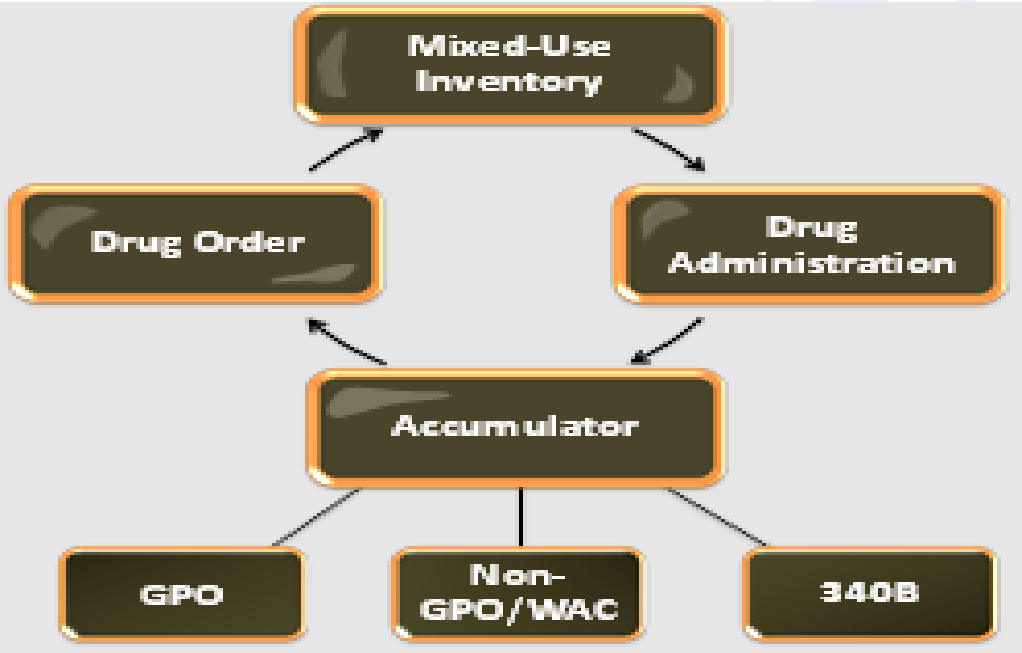
g. Mixed-use inventory replenishment is monitored by using split-billing software. Key points to address appropriate access to wholesaler accounts and split billing software include:

    a. AH identifies all pharmacy purchasing accounts.
    b. AH identifies which accounts are used for each 340B eligible location to purchase 340B drugs
    c. AH places 340B, GPO, and WAC drug orders, based on orders created from the split-billing system.
        a. 340B drugs are ordered at an 11-digit NDC level.
        b. Appropriate processes are in place to ensure proper ordering, tracking, and adjusting of accumulators for controlled substances
    d. AH receives shipments.
    e. AH verifies quantity received with the quantity ordered.
        a. Identifies inaccuracies.
        b. Resolves inaccuracies
        c. Documents resolution of inaccuracies
    f. AH documents manual manipulations to the 340B split-billing accumulator, including reason for manual manipulations.
    g. AH reviews purchasing records with dispensing records biannually to ensure that covered outpatient drugs purchased through the 340B program are used only for 340B eligible patients.
    h. AH staff reports significant discrepancies to AH management within one business day.

i. AH maintains records of 340B – related transactions for a period of 3 years in a readily retrievable format.
    a. These reports are reviewed by Alameda Hospital as part of its 340B oversight and compliance program.

h. Wasted/Expired 340B medication:
    a. AH pharmacy staff documents destroyed or wasted drugs.
    b. AH Pharmacist adjust the 340B accumulators based on reported waste.

i. AH Staff (and/or external vendor) conduct an annual physical inventory.



0. Purchase mixed-use inventory (according to eligible accumulations).
1. Administered and dispensed drugs to patients.
2. Accumulator accumulates drug on an 11-digit NDC match until the unit of use is met, prepares order, uses patient/clinic/prescriber information to determine the appropriate contract for ordering.

GPO	Non-GPO (Non-340B WAC)	340B

GPO/Inpatient class of trade: Inpatient status determined by the hospital at the date/time of administration GPO/Outpatient class of trade: Offsite/unregistered outpatient clinics	Products that do not have an 11-digit NDC match on the 340B contract but are otherwise eligible for 340B purchase Non-340B eligible outpatients, i.e.: Administration or dispensing occurred at a clinic within 4 walls of covered entity, but not 340B eligible Medicaid carve-out outpatients Lost charges or wasted product	Patients met 340B patient definition and received services on an outpatient basis in a 340B registered/participating hospital clinic

- Replenishment drug order(s) are placed according to eligible accumulations.

j. -AH Staff (and/or external vendor) conducts an annual physical inventory.

3. Drug Shortage/340B Price not available

a. Alameda Hospital will purchase covered outpatient drugs at 340B price. During times of Drug Shortages or when 340B price is not available, AH will contact the drug manufacturer.
b. Covered outpatient drug will be purchased on a non-GPO account if the 340B price is not available. If the drug cannot be purchased on a non-GPO account, AH may use GPO alternative only if Alameda Hospital documents and maintains records that all other options have been exhausted.
c. Alameda Hospital must attempt to purchase drug at 340B price every time an order is made.

VI.. Safeguards to Prevent Duplicate Discounts

a. AH is a CA Medi-Cal "Carve in" facility and bills Medicaid per reimbursement requirements, and as reflected its information on the OPA website as Carve in. AH bills Medicaid per Medi-Cal reimbursement requirements, and as such AH has reflected its information on the OPA website/Medicaid Exclusion (http://opanet.hrsa.gov/340B/Views/CoveredEntity/SearchDirectory)
    a. AH informs OPA immediately of any changes to its information on the OPA website/Medicaid Exclusion File
        i. AH is responsible for the accuracy of the information in Medicaid Exclusion File (MEF) The MEF (Medicaid Exclusion File) lists covered entities that have decided to use 340B drugs for their Medicaid patients and to bill Medicaid for those drugs (carve-in). Having this information in the MEF (Medicaid Exclusion File) indicates to the states and manufacturers which drugs are not subject to Medicaid rebates, and helps ensure the prevention of duplicate discounts, as prohibited by statute.

ii. Covered entities are required to ensure that information in the MEF is accurate each quarter and at the time of annual recertification.

b. Alameda Hospital does not in the course of regular business bill Out of State Medicaid and Managed Medicaid for 340B drugs in the hospital mixed-use and retail pharmacy.

c. A UD Modifier is used for physician-administered claims to identify a 340B purchased drug by using the reporting modifier "UD" in conjunction with the procedures code on the state or federal billing form. When a claim is filed with Medicaid for administering drugs purchased under the 340B drug discount program, a modifier "UD" along with the 11-digit National Drug Code (NDC).

VII.. Emergency and Disaster Medication

Flexibility During Emergency:
In the event of a State of Emergency providers may work past term date if necessary due to hospital occupancy.

VIII. Loan/Borrow Processes:

The borrowing and lending process is evaluated based on different criteria, such as 340B status, emergent need, or inventory availability at each pharmacy. See policy: "Borrowing and Loaning Medications Between AHS Inpatient Pharmacies."

IX.. Monitoring and Reporting:

1. Monitoring
    a. The entity uses the process outlined in: 340B Compliance Self-Assessment: Self-Audit Process to Ensure 340B Compliance. Additional monitoring or reporting includes:
        i. Daily monitoring of accrual file upload to wholesaler
        ii. Ongoing monitoring of unreconciled dispenses and wastes
        iii. Ongoing collaboration with Pharmacy IT (Information Technology) to ensure products, units, quantities, prices are up-to-date and correctly represented.

2. 340B Compliance Overview
    a. The 340B Compliance Review summarizes all activities necessary to ensure comprehensive review of 340B compliance at AH. AH staff is responsible and accountable for overseeing this review process, as well as taking corrective actions based upon findings.

		Area of Focus			
Activity	Frequency	AH Eligibility	No Diversion	No Duplicate Discount	GPO Prohibition
Review of all OPA database information for AH, indigent care agreement with state/local government, and Medicare Cost Report (Worksheet E, Part A and Worksheet A), prior to recertification Internal Compliance *Staff responsible: Director of Pharmacy, System 340B Manager & CFO*	Annual	√			
Review of 340B Self-Audit Reports (mixed-use & outpatient pharmacy) *Staff responsible: System 340B Manager, Director of Pharmacy, CFO, COO*	Quarterly		√	√	√
Review of quarterly contract price load *Staff responsible: Director of Pharmacy, System 340B Manager, System 340B Analyst*	Quarterly		√		
Update of prescriber eligibility files with outpatient patient management processing system *Staff responsible: Provider Service Director and EHR IT manager, system 340B manager*	Monthly		√		
Split-Billing software maintenance (CDM-NDC mapping, updates, etc.) *Staff responsible: System 340B Analyst, System 340B Manager*	Daily or Weekly		√		√

b. Quarterly internal audits will be performed by designated pharmacy staff and reviewed by the Director of Pharmacy. AH staff are responsible and accountable for overseeing this review process, as well as taking corrective actions based upon findings.
ii. Mixed- use area/hospital audits:
Audits will include, but not limited to, ensuring the patients meeting 340B eligibility, the charge on administration data is accurate, patient status is outpatient, patient had an order for the medication and was written by an eligible provider and the medication accumulated in the correct account in our virtual inventory records.

2. Reporting Non-Compliance
   a. AH acknowledges that if there is a breach of the 340B requirements, AH may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and depending upon the circumstances, may be subject to the repayment of interest and/or removal from the list of eligible 340B entities.
   b. As AH identifies areas/types of non-compliance related to entity eligibility, diversion, or duplicate discount, AH will notify OPA, and any associated drug manufacturers complete with appropriate documentation/records along with a plan for corrective action.

c. Threshold to self-report:
Violations identified through internal self-audits, independent external audits, or other methods that exceed the 5% threshold and remain non-correctable within the entity - defined period timeframe of review, as defined as Material Breach under this Policy, will be immediately reported to HRSA and applicable manufacturers. The Self-Disclosure Tool included in this Policy may be utilized to assist Covered Entity in self-reporting a Material Breach.

References

1. Section 340B of the Public Health Service Act.
2. Apexus 340B University
3. Apexus 340B Tools https://www.apexus.com/solutions/education/340b-tools
4. HRSA Entity Self-Disclosures: https://www.hrsa.gov/opa/self-disclosures/self-disclosure.html
5. Apexus 340B Self disclosure tool: https://www.340bpvp.com/resource-center/340b-tools
6. Apexus 340B Material Breaching threshold: https://www.340bpvp.com/resource-center/340b-tools

Approvals

		System	HH/SLH/JG/FM	Alameda
Departmental	**Date:**	**6/2025**		
Pharmacy and Therapeutics Committee	**Date:**	**6/2025**		
Clinical Practice Council	**Date:**	**7/2025**		
Medical Executive Committee	**Date:**	**7/2025**		
Board of Trustees	**Date:**	**8/2025**		

ALAMEDA HEALTH SYSTEM	Policy	
	340B DRUG PRICING PROGRAM POLICY MANUAL – FREESTANDING CLINICS	**29942 1**
	LEVEL ☐ System ☐ Site	EFFECTIVE DATE: 7/2025 NEXT REVIEW DATE: 7/2028

Table of Contents

Purpose

This Policy Manual contains the written policies and procedures that Alameda Health System uses to oversee 340B Program operations, provide oversight of contract pharmacies, and maintain a compliant 340B Program.

Background

Section 340B of the Public Health Service Act (1992) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign a pharmaceutical pricing agreement (PPA) with the Secretary of Health and Human Services.

a. This agreement limits the price that manufacturers may charge certain covered entities for covered outpatient drugs.

The 340B Program is administered by the federal Health Resources and Services Administration (HRSA) in the Department of Health and Human Services (DHHS).

Upon registration on the HRSA 340B Database as a participant in the 340B Program, Alameda Health System:

a. Agrees to abide by specific statutory requirements and prohibitions.
b. May access 340B drugs.

340B Policy Statements

Alameda Health System complies with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity. [REFERENCE: Public Law 102-585, Section 602, 340B Guidelines, 340B Policy Releases].

Alameda Health System uses any savings generated from 340B to provide medical services directly to the underserved population of Alameda County.

Alameda Health System has systems/mechanisms and internal controls in place to reasonably ensure ongoing compliance with all 340B requirements.

Alameda Health System maintains auditable records demonstrating compliance with the 340B Program.

a. These reports are reviewed by Alameda Health System every month as part of its 340B oversight and compliance program.

Definitions

Definitions of terms may be found in **340B Glossary of Terms** (https://docs.340bpvp.com/documents/public/resourcecenter/glossary.pdf)

Covered Drug- Wellness clinics do not purchase covered outpatient drugs for its outpatient registered facilities using a Group Purchasing Organization (GPO)

a. The Wellness Clinics interpret the definition of covered outpatient drugs to include – 'An FDA approved prescription drug, an over the counter (OTC) drug that is written on a prescription and a biological product that can be dispensed only by a prescription (other than a vaccine) or FDA-approved insulin.

b. The following drugs and drug categories are excluded from 340B and are GPO exclusion exempt: vaccines, normal saline & water for injection, gases, contrast media/diagnostic agents, large volume fluids without additives, topicals, romiplostim, hyaluronan and hyaluronate derivatives, 503B purchased drugs, cellulose oxidized, state supplied emergency medication (e.g., Covid medications under emergency use approval) manufacturers/labelers that do not participate in 340B program, and bundled items. A detailed list of items and categories can be available through EHR.

References

Each section includes other references to P&Ps, 340B Glossary of Terms, HRSA website, etc. as applicable.

Policy Review, Updates, and Approval

These written policies and procedures will be updated and approved by Alameda Health System staff/committee whenever there is a clarification, or change, in the rules, regulations, or guidelines to the 340B Program requirements. Otherwise, the policy will be reviewed and approved annually.

COVERED ENTITY ELIGIBILITY

Policy: Alameda Health System must meet the requirements of 42 USC §256b(a)(4)(A) to be eligible for enrollment in, and the purchase of drugs through, the 340B Program.

Purpose: To ensure Alameda Health System eligibility to participate in the 340B Program.

Procedure:

1. Alameda Health System basis for 340B eligibility is determined by the following:
    a. Alameda Health System – Eastmont Wellness Center, Hayward Wellness Center, and Newark Wellness Center have a designation as a Federally Qualified Health Center (FQHC) which is consistent with conferring 340B eligibility
        i. The defining legislation for Federally Qualified Health Centers (under the Consolidated Health Center Program) is Section 1905(l)(2)(B) of the Social Security Act.
        ii. Alameda Health System additionally qualifies each Wellness Center through inclusion in our HRSA Scope of Project Form 5A: Services Provided and Form 5B: Service Sites
        iii. AHS reviews Form 5A and 5B on a yearly basis, and as needed, to ensure that each site and service provided at the Wellness Centers is reflected
2. Alameda Health System has identified locations where 340B drugs are dispensed or prescribed:

Within the four walls of the child entities (Eastmont, Hayward, and Newark Wellness Centers)

- Eastmont Wellness Clinic: CH09087B
- Newark Wellness Clinic: CH09087C
- Hayward Wellness Clinic: CH09087W

3. Alameda Health System ensures that the HRSA 340B Database is complete, accurate, and correct for all 340B eligible locations including the parent entity, service sites, and contract pharmacies. [Refer to Alameda Health System Policy and Procedure "340B Program Enrollment, Recertification, and Change Request"].
    a. All service sites that use 340B drugs (as identified in #2 above) are registered on Alameda Health System's HRSA 340B Database.
    b. All main addresses, billing and shipping addresses, the authorizing official, and the primary contact information are correct and up to date.
    c. Alameda Health System regularly reviews its 340B Database records [Refer to Alameda Health System Policy and Procedure "340B Program Compliance Monitoring and Reporting"].
    d. Alameda Health System informs HRSA immediately of any changes to its information by updating the HRSA 340B Database quarterly.

i. See Appendix [1] – HRSA Database Screenshot

https://340bopais.hrsa.gov/

4. Alameda Health System annually recertifies information on HRSA's 340B Database. [Refer to Alameda Health System Policy and Procedure "340B Program Enrollment, Recertification, and Change Request"].

340B PROGRAM ENROLLMENT, RECERTIFICATION, AND CHANGE REQUESTS

Policy: Eligible Federally Qualified Health Centers must be registered on, and maintain the accuracy of, the HRSA 340B Database to participate in the 340B Program.

Purpose: To ensure Alameda Health System registration on, and accuracy of, the HRSA 340B Database.

References:

340B Drug Pricing Program: On-line registration instructions at https://opanet.hrsa.gov/OPA/CERegister.aspx?isnew=true

Registration dates:

- January 1–January 15 for an effective start date of April 1
- April 1–April 15 for an effective start date of July 1
- July 1–July 15 for an effective start date of October 1
- October 1–October 15 for an effective start date of January 1

340B Contract Pharmacy Guidelines https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf

Procedures:

Enrollment

1. Alameda Health System is eligible to participate in the 340B Program [Refer to Alameda Health System Policy and Procedure "Covered Entity Eligibility"].
2. Alameda Health System has identified upcoming registration dates and deadlines.
3. Alameda Health System has identified authorizing official and primary contact.
4. Alameda Health System has available the required document:
    a. The grant conferring 340B eligibility
5. Alameda Health System has completed registration on the HRSA 340B Database

Recertification Procedure

1. Alameda Health System annually recertifies information on the HRSA 340B Database.
    a. Chief Administrative Officer for Ambulatory completes the annual recertification by following the directions in the recertification email sent from HRSA prior to the stated deadline.

i. Alameda Health System submits specific recertification questions to 340b.recertification@hrsa.gov.

Enrollment Procedure: New Outpatient Facilities

1. Alameda Health System determines that a new service site or facility is eligible to participate in the 340B Program.
    a. The criteria used include that the service site must be identified in the grant, have outpatient drug use, and have patients who meet the 340B patient definition.

Enrollment Procedure: New Contract Pharmacy(ies)

1. Alameda Health System has a signed contract pharmacy services agreement, containing the 12 essential compliance elements in the Contract Pharmacy Guidance, in place between the entity and contract pharmacy prior to registration on the HRSA 340B Database.
https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf
    a. Alameda Health System's legal counsel has reviewed the contract and verified that all federal, state, and local requirements have been met.

2. Alameda Health System has contract pharmacy oversight and monitoring policy and procedure developed, approved, and implemented. [Refer to Alameda Health System Policy and Procedure "Contract Pharmacy Oversight Management"].

3. Alameda Health System's authorizing official or designee completes the online registration during one of four registration windows.
    a. Within 15 days from the date of the online registration, the authorizing official certifies online that the contract pharmacy registration request was completed.
        ii. Contract pharmacy's responsible representative may be the owner, president, CEO, COO, or CFO.

4. Alameda Health System begins using the contract pharmacy services arrangement only on or after the effective date shown on the HRSA 340B Database.

Changes to Alameda Health System's Information in HRSA 340B Database Procedure

1. Alameda Health System notifies HRSA immediately of any changes to Alameda Health System's eligibility to participate in the 340B Drug Program (such as termination of grant or change in designation).
    a. Alameda Health System will stop the purchase of 340B drugs as soon as the change in 340B eligibility is identified. [Refer to Alameda Health System Policy and Procedure "Covered Entity Eligibility"].
    b. Alameda Health System's authorizing official will complete the online change request as soon as a change in eligibility is identified.
        i. Alameda Health System will expect changes to be reflected within two weeks of submission of the changes/requests.

2. Alameda Health System will notify HRSA immediately of any changes to Alameda Health System's information on its HRSA 340B Database. [Refer to Alameda Health System Policy and Procedure "Covered Entity Eligibility"].

3. Alameda Health System's authorizing official will complete the online change request as soon as a change in eligibility is identified.
    a. Alameda Health System will expect changes to be reflected within about 4 weeks of submission of the changes/requests.

PATIENT ELIGIBILITY/DEFINITION

Policy: Per the Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 340B drugs are to be provided only to individuals eligible to receive 340B drugs from covered entities.

Purpose: Alameda Health System ensures that 340B drugs are dispensed/administered/prescribed only to eligible patients.

Definitions:

Administer: Give a medication to an individual, typically in a hospital or a clinic, based on a health care provider's order.

Dispense: Provide a medication, typically in a hospital or a clinic, based on a health care provider's order to be administered to a patient.

Prescribe: Provide a prescription for a medication to an individual to be filled at an outpatient pharmacy.

Procedure:

1. Alameda Health System validates site eligibility.
    a. Refer to Alameda Health System's Policy and Procedure "Covered Entity Eligibility".
    b. All eligibility is verified by HRSA Scope of Services Form 5B

2. Alameda Health System determines patient status.
    a. Patient must be in outpatient status at the time the medication is dispensed/administered at Alameda Health System or a contract pharmacy listed on the HRSA 340B Database.

3. Alameda Health System maintains records of individual's health care.
   a. Freestanding Clinic (Eastmont Wellness, Hayward Wellness, and Newark Wellness) medical records consist of EPIC electronic health records, which are maintained by Alameda Health System.

4. Alameda Health System determines provider eligibility.
   a. Provider is employed by the entity, under contractual or other arrangements with the entity, and the individual receives a health care service (within the scope of grant/designation for which 340B status was conferred) from this professional such that the responsibility for care remains with the entity.
      i. All providers prescribing for 340B eligible patients are employees of Alameda Health System or are contracted through East Bay Medical Group
      ii. Alameda Health System maintains an active eligible provider list through Wellpartner 340B contract pharmacy management system.
         a. Weekly eligibility obtained from current Provider Enrollment Roster search and updated in Wellpartner.
      iii. Wellpartner provider list is part a shared online database with contracted pharmacies listed.
      iv. Eligible provider lists are updated at least monthly and upon notification of provider status changes from the provider or clinic leadership.
      v. Contract Pharmacies have real time online access to eligible provider list through Wellpartner.
      vi. Refer to online Wellpartner 340B contract pharmacy management portal for the location of current eligible provider list.
      vii. Pharmacists and dieticians who are employed by Alameda Health System practice a collaborative practice agreement within an eligible clinic are considered eligible providers.

5. Encounter/prescription eligibility for Disease State management and/or MTM:
   a. The responsibility for the health care service that result in the use of, or prescription for, 340B drugs must remain with covered entity.
   b. Prescriptions will be deemed eligible if they meet one of the following criteria:
      i. A prescription is derived from a qualifying outpatient health care service documented within the previous 36 months from the date of fill.
      ii. A qualifying outpatient health care service occurs within 30 days after the date of fill where the prescription is documented in the service summary.
      iii. The window for establishing 340B eligibility through care provided by The Wellness Clinics is based on a 36 month look back period form the date the prescription is filled.
      iv. Eligible encounter: Any encounter that support a continuing patient-provider relationship may include, but are not limited to office visit, telehealth appointments, refill requests, lab orders, imaging requests, and medication management consults. Any documented interaction that reasonably

demonstrates the patient remains under the ongoing care of the Wellness Clinics maybe considered valid to support 340B eligibility.

6. Alameda Health System determines patient's Medicaid status prior to administration/dispensing [Refer to Alameda Health System's Policy and Procedure "Prevention of Duplicate Discounts"].

PREVENTION OF DUPLICATE DISCOUNTS

Policy: 42 USC §256b(a)(5)(A)(i) prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must have mechanisms in place to prevent duplicate discounts.

Purpose: To ensure that Alameda Health System is preventing duplicate discounts.

Procedure: ***Alameda Health System has elected to administer 340B drugs to its Medicaid patients (carve-in).***

Medicaid Carve-In

1. Alameda Health System administers 340B purchased drugs to Medicaid patients (carve-in).
    a. Alameda Health System – Eastmont Wellness Center, Hayward Wellness Center, and Newark Wellness Center has answered "yes" to the question, "Will the covered entity dispense 340B purchased drugs to Medicaid patients?" on 340B OPAIS.
2. Alameda Health System – Eastmont Wellness Center, Hayward Wellness Center, and Newark Wellness Center bills Medicaid per state Medicaid reimbursement requirements for all physician-administered medications:
    a. Medicaid Provider Numbers for all state Medicaid agencies billed and applicable National Provider Identifiers (NPIs) for the child sites are listed on the 340B OPAIS Medicaid Exclusion File.
        i. Eastmont Wellness Center:
            1. FQHC – NPI#: 1104959089 MPN: FHC11783G
            2. Family PACT – NPI#: 1750582557 MPN: HAP11783G
            3. Cancer Detection – NPI#: 1841491644 MPN: BCP11783G
            4. Medicare – NPI#: 1932300738 MPN: ZZZ77815Z
        ii. Hayward Wellness Center:
            1. FQHC – NPI#: 1033241633 MPN: FHC11797G
            2. Family PACT – NPI#: 1306047196 MPN: HAP11797G
            3. Cancer Detection – NPI#: 1114128915 MPN: BCP11797G
            4. Meidcare – NPI#: 1023219821 MPN: ZZZ77817Z

iii. Newark Wellness Center:
   1. FQHC – NPI#: 1922131804 MPN: FHC11799G
   2. Family PACT – NPI#: 1689875478 MPN: HAP11799G
   3. Cancer Detection – NPI#: 1770784563 MPN: BCP11799G
   4. Medicare – NPI#: 1497956288 MPN: ZZZ77818Z

b. All billing claims from Alameda Health System containing line items for medications purchased through 340B accounts that are administered to patients during an office visit have a UD modifier added prior to submission
   i. An internal collaborative process, which utilizes both automated and manual practices, ensures that the UD is correctly placed.

c. Alameda Health System maintains a Charge Drug Master (CDM) which contains the 340B purchasing status for all medications available for physician administration at Eastmont Wellness, Hayward Wellness, and Newark Wellness.

3. Alameda Health System informs HRSA immediately of any changes in its MEF information by updating 340B OPAIS before the 15th of the month prior to the quarter when the change take effect (note that this is a different timeframe than quarterly registration).

For example, changes made to 340B OPAIS before March 15 would become effective on April 1.

4. Alameda Health System regularly reviews its 340B OPAIS Medicaid Exclusion File records [Refer to Alameda Health System's Policy and Procedure "340B Program Compliance Monitoring and Reporting."
5. Medicaid reimburses Alameda Health System for 340B drugs per state policy and does not seek rebates on drug claims submitted by Alameda Health System.
6. Wellness clinics do not in the course of regular business bill Out of State Medicaid and Managed Medicaid for 340B drugs for clinic and pharmacy services.

Contract Pharmacies

1. Alameda Health System's contract pharmacies carve-out.

340B PROGRAM ROLES AND RESPONSIBILITIES

Policy: Covered entities participating in the 340B Program must ensure program integrity and compliance with 340B Program requirements.

Purpose: To identify key stakeholders and determine their roles and responsibilities in maintaining 340B Program integrity and compliance.

Procedure:

1. Alameda Health System's key stakeholders' roles and responsibilities with the 340B Program:
    a. Chief Financial Officer and/or VP of Finance:
        i. Responsible as the principal officer in charge for the compliance and administration of the program
        ii. Must account for savings and use of funds to provide care for the indigent under the indigent care agreement
        iii. Responsible for communication of all changes to the Medicare Cost report regarding clinics or revenue centers of the cost report
        iv. Responsible for communication of all changes to Medicaid reimbursement for pharmacy services/products that impact 340B status
    b. Chief Administrative Officer – Ambulatory:
        i. Responsible for attesting to the compliance of the program in form of recertification
        ii. Accountable agent for 340B compliance
    c. System Director of Pharmacy:
        i. Agent of the CFO responsible to administer the 340B program to fully implement and optimize appropriate savings and ensure current policy statements and procedures are in place to maintain program compliance
        ii. Must maintain knowledge of the policy changes that impact the 340B program which includes, but not limited to, HRSA/OPA rules and Medicaid changes
    d. System Ambulatory Care Pharmacy Manager:
        i. Must coordinate constant knowledge of any change in clinic eligibility/information
        ii. Day to day manager of the program
        iii. Responsible for documentation of policy and procedures
        iv. Assure appropriate safeguards and system integrity
        v. Assure compliance with 340B program requirements of qualified patients, medications, providers, vendors, payors, and locations.
        vi. Review and refine 340B cost savings report detailing purchasing, and replacement practices, as well as dispensing patterns
    e. Pharmacy Technician
        i. Responsible for ordering all medications from the specific wholesaler accounts as appropriate
        ii. Manage purchasing, receiving and inventory control processes
        iii. Continuously monitor product min/max levels to effectively balance product availability and cost efficient inventory control
        iv. Monitor ordering processes, integrating most current pricing from wholesaler, analyze invoices, shipping, and inventory processes
        v. Maintain system databases to reflect changes in the drug formulary or product specification
        vi. Responsible for maintenance and testing of Wellpartner 340B management portal

2. Alameda Health System has established a 340B Oversight Committee that is responsible for the oversight of the 340B Program, or other similar oversight process, including that the committee:
    a. Executive Sponsor: COO
    b. Authorizing Officials: CAO Ambulatory, COO AHS
    c. Pharmacy Leaders: System Director of Pharmacy, System Ambulatory Care Pharmacy Operations Mangaer
    d. 340B Pharmacy Technician Support Staff: Freestanding Clinic Pharmacy Technicians
    e. Finance
    f. Compliance
    g. General Counsel

3. Alameda Health System's 340B Oversight Committee:
    a. Meets on a quarterly basis.
    b. Reviews 340B rules/regulations/guidelines to ensure consistent policies/procedures/oversight throughout the entity.
    c. Identifies activities necessary to conduct comprehensive reviews of 340B compliance.

i. Ensure that the organization meets compliance requirements of program eligibility, patient definition, 340B drug diversion, and duplicate discounts via ongoing multidisciplinary teamwork.

ii. Integrate departments such as information technology, legal, pharmacy, compliance, and patient financial services to develop standard processes for contract/data review to ensure program compliance.

    d. Oversees the review process of compliance activities, as well as taking corrective actions based on findings.
        i. 340B Oversight Committee assesses if the results are indicative of a material breach (Refer to Alameda Health System's Policy and Procedure "340B Non-Compliance/Material Breach"].
    e. Reviews and approves work group recommendations (process changes, self-monitoring outcomes and resolutions).

340B PROGRAM EDUCATION AND COMPETENCY

Policy: Program integrity and compliance are the responsibility of all 340B key stakeholders. Ongoing education and training are needed to ensure that these 340B key stakeholders have the knowledge to guarantee compliant 340B operations.

Purpose: To establish 340B education and competency requirements for Alameda Health System's 340B key stakeholders based on their roles and responsibilities in the 340B Program.

Procedure:

1. Alameda Health System determines the knowledge and educational requirements for each 340B Program role [Refer to Alameda Health System's Policy and Procedure "340B Program Roles and Responsibilities"].

2. 340B key stakeholders complete initial basic training upon hire.
    a. Via the link below https://www.brainshark.com/apexus/TopFive340BBasics
    b. Expected to attend 340B University or view the 340B University OnDemand modules on the Apexus website within one year of establishment of 340B role

3. 340B key stakeholders complete additional training as identified in #1 above.

4. Alameda Health System provides educational updates and training, as needed based upon 340B policy and procedure changes, updates in HRSA guidance, changes of roles and responsibilities.

5. Alameda Health System conducts annual verification of 340B Program competency. See Appendix [2]

6. Training and education records are maintained per organizational policy and available for review.

INVENTORY MANAGEMENT

Policy: Alameda Health System must be able to track and account for all 340B drugs to ensure the prevention of diversion.

Purpose: Ensure the proper procurement and inventory management of 340B drugs.

Background:
340B inventory is procured and managed in the following settings:

- Clinic site administration
- Contract pharmacies

Inventory methods for each of the above areas within the entity shall be described within the inventory management policy and procedure.

Alameda Health System uses one of the following inventory methods at each of the above named settings:

a. Stocks only 340B inventory – Clinic site.
b. Electronically (virtual) separates 340B and non-340B purchased inventory – Contract Pharmacies

c. In extraordinary circumstances, if a non-340B purchased drug is procured in the clinic sites, AHS will maintain physically separated inventory.

Pharmacists and technicians dispense 340B drugs only to patients meeting all the criteria in [Refer to Alameda Health System's Policy and Procedure "Patient Eligibility/Definition"].

References:
Apexus Tool: 340B Compliance and the Controlled Substance Ordering System (CSOS) may be used to articulate compliance solutions in this area:
https://docs.340bpvp.com/documents/public/resourcecenter/340B_Compliance_CSOS.pdf

Procedure:

Physical inventory (340B only) is maintained at Alameda Health System Freestanding Clinics (Eastmont Wellness, Hayward Wellness, Newark Wellness)

1. Alameda Health System identifies all Wholesaler accounts used for purchasing drugs for clinic administration.

2. Alameda Health System maintains only 340B inventory in its floor stock/clinic medication rooms at each clinic site. Vaccine products are excluded from 340B drug purchasing and inventory at each clinic site.

3. Alameda Health System Pharmacists or Pharmacy Technicians perform regular inventory reviews and shelf inspections of periodic automatic replenishment (PAR) levels to determine daily purchase order. Nursing staff will notify appropriate pharmacy staff when floor stock medication is out or below PAR levels to assist in timely ordering of medication for clinic administration.

4. Alameda Health System Pharmacy Technician support staff place 340B inventory replenishment orders from Cardinal Wholesaler as needed based on inventory reviews and shelf inspections.

5. A pharmacist, pharmacy technician, registered nurse, physician, or Advanced Practice Provider will sign in for the medication received. Documentation of receipt will include the following:
   a. The date and time delivery was received
   b. Description of medication /supplies received
   c. Quantity of delivered items
   d. Signature and title of person receiving and logging in delivery.

6. Alameda Health System verifies quantity received with quantity ordered.

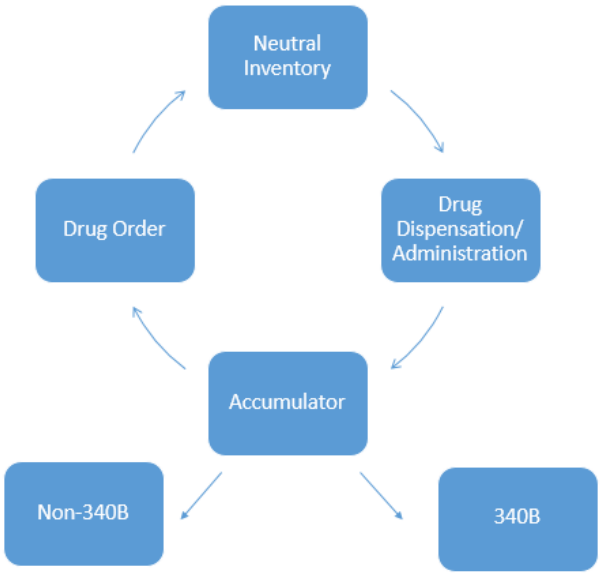
a. Identifies inaccuracies between online Wholesaler order and received invoice upon delivery.
b. Reports and resolves inaccuracies with the Wholesaler.
c. Documents resolution of inaccuracies on the invoice or through other written or electronic communication with the Wholesaler.

7. Alameda Health System maintains records of 340B-related transactions for a period of 5 years in a readily retrievable and auditable format. Online Wholesaler orders are kept electronically through the Cardinal Health account. Receipt/invoice physically stored on site for a period of 5 years.
   a. Random audits of these records are reviewed by Alameda Health System monthly as part of its 340B oversight and compliance program.

8 Wasted/Expired 340B medication:

a. Wellness Clinic pharmacy staff documents destroyed or wasted drugs.
b. Wellness Clinic pharmacy staff monitors unreconciled dispenses and wastes on a monthly basis.

Inventory replenishment system (340B/non-340B) is maintained at Contract Pharmacies



1. Wellpartner – 340B Management 3rd party vendor identifies all accounts used for purchasing drugs at contract pharmacies for 340B and non-340B.
2. Alameda Health System purchases inventory according to eligible accumulations for 340B replenishment at contract pharmacies.
3. Contract Pharmacies dispense drugs to patients.

4. 340B Management Software (Wellpartner) accumulates drug utilization based upon patient eligibility including service location and provider information. This accumulation occurs at the 11-digit NDC level and a full package size will be accumulated before replenishment by the 340B administrator at each site.

340B	Non-340B
Patients met 340B patient definition and received services on an outpatient basis in a 340B registered/participating hospital clinic	-Products that do not have an 11-digit NDC match on the 340B contract but are otherwise eligible for 340B purchase -Products that currently are not available (e.g., drug shortages) such that an 11-digit NDC match is not available -Products for Medicaid eligible patients

CONTRACT PHARMACY OPERATIONS

Policy: Alameda Health System remains responsible for ensuring that its contract pharmacies operations comply with all 340B Program requirements, such that the covered entity remains responsible for the 340B drugs it purchases and dispenses through a contract pharmacy.

Purpose: To ensure that Alameda Health System remains responsible for all 340B drugs used by its contract pharmacies.

Reference:

Federal Register / Vol. 61, No. 165 / Friday, August 23, 1996 / Notices
https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf

Background:

Alameda Health System uses contract pharmacy services in accordance with HRSA requirements and guidelines.

Alameda Health System has obtained sufficient information from the contract pharmacy contractor to ensure compliance with applicable policy and legal requirements.

The signed contract pharmacy services agreements comply with 12 contract pharmacy essential compliance elements.

Procedure:

1. Alameda Health System contracts with Wellpartner to facilitate both the design and implementation of the 340B contract pharmacy program.

2. Alameda Health System has a written contract in place for each contract pharmacy location:
    a. Garfield Beach CVS, L.L.C. DBA: CVS Pharmacy # 8431 – 7200 Bancroft Ave, Oakland, CA 94605
    b. Longs Drug Stores California, L.L.C. DBA: CVS Pharmacy # 9635 – 1550 E 14th St, San Leandro, CA 94577
    c. Longs Drug Stores California, L.L.C. DBA: CVS Pharmacy # 9622 – 243 W Jackson St, Hayward, CA 94544
    d. Longs Drug Stores California, L.L.C. DBA: CVS Pharmacy # 9494 – 35080 Newark Blvd, Newark, CA 94560

3. Alameda Health System registers each contract pharmacy location on the HRSA 340B Database prior to the use of 340B drugs at that site.

4. Alameda Health System uses a replenishment model using an 11-digit to 11-digit NDC match.
    a. Non-replenishment 340B inventory is never stored at CVS contract pharmacies, as all 340B stock is supplied through the replenishment model.
5. 340B-eligible prescriptions are presented to CVS contract pharmacies via (e-prescribing, hard copy, fax, or phone).
    a. CVS staff verify patient, prescriber, and outpatient clinic eligibility via the Wellpartner online portal.
    b. Updates are made to this mechanism by Alameda Health System Pharmacy Technician 340B support staff yearly or on demand based on patient, provider, or contract pharmacy request.

6. CVS contract pharmacies dispense prescriptions to 340B eligible patients using CVS non-340B drugs.

7. Alameda Health System implements a bill-to, ship-to arrangement with the contract pharmacies.
    a. CVS contract pharmacies order 340B drugs on behalf of AHS, based on eligible accumulation, as determined by the Wellpartner portal, through Cardinal Health Wholesaler.
        i. Orders are triggered by the usage of package size of covered drugs determined by 11-digit NDC
        ii. Replenishment orders through Cardinal Wholesaler Order Express occur daily (Monday through Friday)

iii. Wholesaler notifies Alameda Health System Staff of medications shipped to CVS contract pharmacies.

b. Invoices are billed to Alameda Health System.

8. CVS contract pharmacies receive 340B drug shipment. Orders are received by a Pharmacist, Pharmacy Technician, or other CVS authorized pharmacy staff.

9. CVS contract pharmacies verify quantity received with quantity ordered.
   a. Identifies inaccuracies.
   b. Resolves inaccuracies with Wholesaler.
   c. Documents resolution of inaccuracies.

10. CVS contract pharmacies/Wellpartner notifies Alameda Health System if CVS doesn't receive 11-digit NDC replenishment order within 90 days of original order fulfillment request.
    a. AHS will reimburse CVS Contract Pharmacies for the cost of such drugs (true-up)

11. Alameda Health System reimburses CVS contract pharmacies at a pre-negotiated rate per fill for such drugs.

12. Alameda Health System is able to review the invoice for drugs shipped to its contract pharmacies through Wellpartner 340B management online portal.

13. Alameda Health System pays invoice to Cardinal for all 340B drugs.

14. CVS contract pharmacies (through Wellpartner online portal) provide Alameda Health System access to all pertinent reimbursement accounts and dispensing records.
    a. Pharmacy Technician 340B support staff retrieve and review 340B purchases twice monthly (1st and the 15th of each month)

15. CVS contract pharmacies adjust claims when variance or discrepancy has occurred.
    a. CVS uses approved methods with knowledge and agreement of Alameda Health System regarding reconciliation between inventory and invoices with adjustments as necessary to match NDC or cost changes.
    b. Claim adjustments may occur only within 30 days of original billing and not without prior notice and approval of Alameda Health System.

16. CVS contract pharmacies will not use 340B drugs for Medicaid patients (carve-out):
    a. CVS contract pharmacies will only dispense 340B drugs to patients who are eligible in the Wellpartner 340B management online portal.
    b. Eligible patients include only those who have active HealthPAC coverage. This is a Health Program of Alameda County that provides medical and prescription coverage to those who:

i. Are residents of Alameda County
ii. Have a gross monthly income at or below the 200% Federal Poverty Level
iii. Not be enrolled or eligible for full-scope Medicaid coverage
iv. Not be enrolled in a private or employer-based insurance

c. Wellpartner does not count 340B drug accumulation for Medicaid patients and therefore prevent(s) duplicate discounts for outpatient prescriptions, including those that are billed to the AIDS Drug Assistance Program (ADAP).

340B NONCOMPLIANCE/ MATERIAL BREACH

Policy: Alameda Health System is responsible for contacting HRSA as soon as reasonably possible if there is any material breach or any instance of noncompliance with any of the 340B Program requirements.

Purpose: To define Alameda Health System's material breach of 340B compliance and self-disclosure process.

Definitions:

Materiality: A convention within auditing/accounting pertaining to the importance/significance of an amount, transaction, and/or discrepancy.

Threshold: The point that must be exceeded, as defined by the covered entity, resulting in a material breach.

Reference:
340B University: Defining Material Breach Documentation Tool
https://docs.340bpvp.com/documents/public/resourcecenter/Establishing_Material_Breach_Threshold.pdf

Procedure:

1. AHS defines a material breach of compliance that would require self-disclosure as (1) a violation(s) that exceeds 5% of total clinic drug purchases or contract pharmacy spend and (2) remain non-correctable within 30 days.
    a. Alameda Health System ensures that identification of any threshold variations occurs among all its 340B settings, including the Freestanding Clinics (Eastmont Wellness, Hayward Wellness, Newark Wellness) and CVS contract pharmacies.

2. Alameda Health System assesses materiality:
    a. Violations identified through internal self-audits, independent external audits, or other methods that exceed the 5% threshold and remain non-correctable within the entity-defined period timeframe of review, will be immediately reported to HRSA and applicable manufacturers.

b. Pharmacy Technician 340B support staff will coordinate assessment with necessary parties (including but not limited to Wellpartner, CVS Contract Pharmacies, AHS 340B Financial Department representatives, clinic staff, and the 340B oversight committee)
a. Alameda Health System maintains records of materiality assessments for a minimum of 5 years.

3. Alameda Health System reports identified material breach immediately to HRSA and applicable manufacturers.
    a. Alameda Health System acknowledges that if there is a breach of the 340B requirements, it may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and depending upon the circumstances, may be subject to the payment of interest and/or removal from the list of eligible 340B entities.
    b. As Alameda Health System identifies areas of non-compliance or material breach it will notify OPA and any associated drug manufacturers complete with appropriate documentation/records along with a plan for corrective action.
    c. Maintain records of material breach violations, including manufacturer resolution correspondence, as determined by organization policy.

340B PROGRAM COMPLIANCE MONITORING AND REPORTING

Policy: Alameda Health System is required to maintain auditable records demonstrating compliance with 340B Program requirements.

Purpose: To provide an internal monitoring program to ensure comprehensive compliance with the 340B Program.

Procedure:

1. Alameda Health System has developed an internal audit plan approved by the internal compliance officer or as determined by organizational policy.
2. Alameda Health System and the 340B Oversight Committee annually reviews the following items to ensure the accuracy of the information for the parent site and contract pharmacies:
    a. HRSA 340B Database
    b. HRSA Scope of Services Form 5A and 5B
    c. 340B Policies and Procedures
    d. Contracts with outside pharmacies
    e. Employee education compliance

3. Alameda Health System audits purchasing records, dispensing records, and patients' health care records monthly to ensure that covered outpatient drugs purchased through the 340B Program are prescribed by eligible providers, dispensed or administered only to patients eligible to receive 340B drugs and that any variances are not the result of diversion

a. Pharmacy Technician 340B support staff performs a monthly random audit of 10-20 high cost/random prescriptions using the Wellpartner 340B management online portal self-audit tool and clinic records for each site, which includes Cardinal purchasing records.

4. Alameda reconciles dispensing records and Medicaid billing practices to demonstrate that Alameda Health System practice is following the Medicaid billing question on the HRSA 340B Database (carve-out)

5. Alameda Health System 340B Oversight Committee reviews the internal audit results quarterly.
   a. Committee to assess if audit results are indicative of a material breach [Refer to Alameda Health System's Policy and Procedure "340B Noncompliance/Material Breach"].

6. Alameda Health System maintains records of 340B-related transactions for a period of 5 years in a readily retrievable and electronic auditable format located on the Alameda Health System shared drive.

CONTRACT PHARMACY OVERSIGHT AND MONITORING

Policy: Alameda Health System is required to provide oversight of their contract pharmacy arrangements to ensure ongoing compliance. The covered entity has full accountability for compliance with all requirements to ensure eligibility and to prevent diversion and duplicate discounts. Auditable records must be maintained to demonstrate compliance with those requirements.

Purpose: To ensure that Alameda Health System maintains 340B Program integrity and compliance at its CVS contract pharmacies.

Reference:
Federal Register / Vol. 75, No. 43 / Friday, March 5, 2010 / Notices
https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf

Procedure:

1. Alameda Health System conducts monthly internal reviews of each registered contract pharmacy for compliance with 340B Program requirements. The following elements will be included when conducting self-audits of contract pharmacies to ensure program compliance:
   a. Prescription is written from a site of care that is registered on the HRSA 340B Database
   b. Patient eligibility: The episode of care that resulted in the 340B prescription is supported in the patient's medical record.

c. Provider eligibility: The prescribing provider is employed, contracted, or under another arrangement with the Alameda Health System at the time of writing the prescription so that the entity maintains responsibility for the care.
d. An 11-digit NDC match can be documented for accumulation and/or replenishment of a 340B dispensation (virtual inventory).
e. Alameda Health System can document that no prescriptions processed had Medicaid listed as the primary payer.

2. Alameda Health System conducts independent audits of each registered contract pharmacy for compliance with the 340B Program requirements.
   a. Independent audits will include reviews of:
      i. 340B eligibility.
      ii. 340B registration.
      iii. Documented policies and procedures.
      iv. Inventory, ordering, and recordkeeping practices for all 340B accounts.
      v. Testing of claims sample to determine any instance of diversion or duplicate discounts in a set period of time.

3. Alameda Health System has mechanisms in place to demonstrate compliance with all state Medicaid billing requirements to prevent duplicate discounts at all sites. All clinic sites and Contract Pharmacies are Medicaid Carve-out.

4. Alameda Health System 340B Oversight Committee reviews independent audit results at quarterly committee meetings.
   a. Assess if audit results are indicative of a material breach [Refer to Alameda Health System's Policy and Procedure "340B Noncompliance/Material Breach"].

5. Alameda Health System maintains records of 340B-related transactions for a period of 5 years in a readily retrievable and auditable format located on the Alameda Health System shared drive.

PRIME VENDOR PROGRAM (PVP), ENROLLMENT, AND UPDATES

Policy: The purpose of the Prime Vendor Program (PVP) is to improve access to affordable medications for covered entities and their patients.

Purpose: Assist Alameda Health System's participation in the PVP to receive the best 340B product pricing, information, and value-added products.

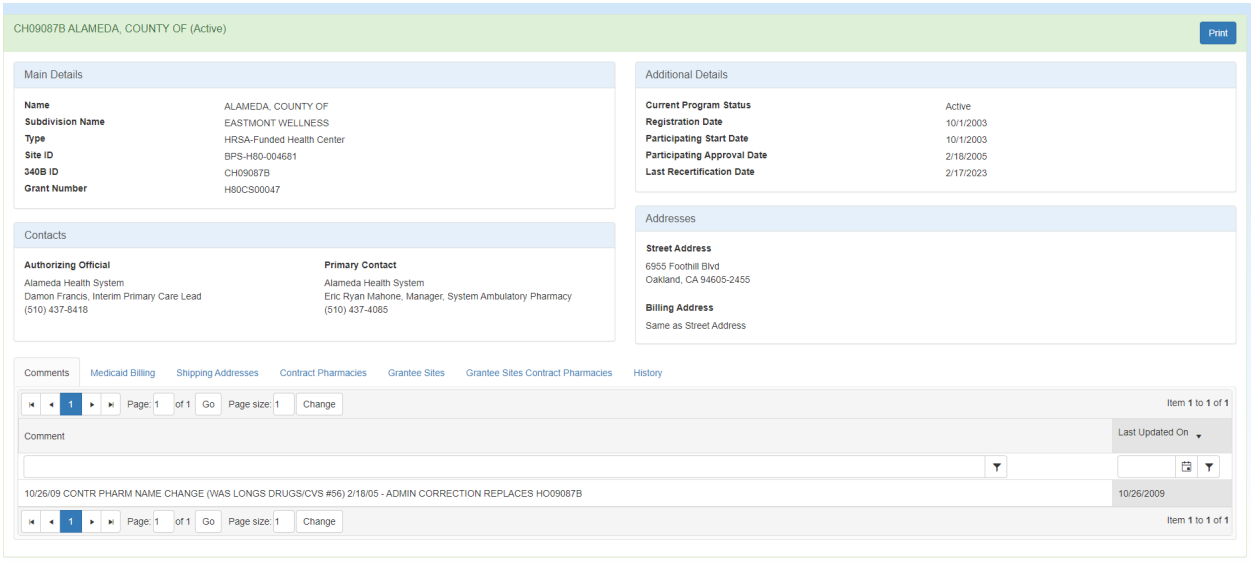
Procedure:

Enrollment in PVP:

1. Alameda Health System has completed online 340B Program registration with HRSA for Eastmont Wellness, Hayward Wellness, and Newark Wellness.

Update PVP Profile:

1. Alameda Health System will update PVP profile yearly through accessing https://members.340bpvp.com/webMemberProfile.aspx.
    a. Find a list of your facilities.
        i. Click on the 340B ID number hyperlink to view or change profile information for that facility.
    b. Update HRSA Information:
        i. Complete the 340B Change Form as detailed above.
            a) After the HRSA 340B Database has been updated, the PVP database will be updated during the nightly synchronization.
2. Alameda Health System updates the 340B Prime Vendor Program (PVP) Participation Information yearly for Eastmont Wellness, Newark Wellness, and Hayward Wellness.



Approvals:

		System
System Pharmacy & Therapeutics	Date:	6/2025
Clinical Practice Committee	Date:	7/2025
Medical Executive	Date:	7/2025
Board of Trustees	Date:	8/2025

ALAMEDA HEALTH SYSTEM

AVOIDING DUPLICATE PRN "As Needed" POLICY

Site	Alameda Health System	***Previous Revision Dates***	
Effective Date	7/2025	***Date Revised:***	6/2025
Document Owner	MGR SYS MED SAFETY-CLIN PHARM	**Next Review Date:**	6/2028
Executive Responsible	DIRECTOR, PHARMACY		

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PURPOSE

To identify medications and their PRN indication, to allow timely processing of medication orders, and to reduce the need for order clarifications in order to ensure patient medication safety.

POLICY STATEMENT

PRN, or "As Needed" medication orders are orders which are administered based on the occurrence of a specific indication or symptom. The Alameda Health Systems Pharmacy Services will, with the approval of the Pharmacy & Therapeutics Committee, identify certain medications and their PRN indication. The Department of Pharmacy Services will maintain and update this list as needed.

PROCEDURE

1. All PRN orders shall contain the following information:
   a) Name of medication
   b) Route
   c) Strength
   d) Frequency (if order without frequency is from an orderset, exclude those from this P&P. Submit request to change orderset as needed instead)
   e) Indication (and parameter if appropriate, e.g. SBP, HR, etc.)
   i.e. Mylanta 30ml PO Q4HR PRN Cramping

2. All PRN orders without specific name, strength, and frequency will be clarified by a pharmacist with the physician and reordered in the electronic health record.

3. All PRN medication orders must contain indications for use. If not stated in the original physician's order, the following indications for use will automatically be interpreted for each drug using Table 1.

4. PRN orders without an indication for medications that are not on Table 1 below will be clarified by a pharmacist with the physician and documented in the electronic health record.

5. PRN orders with therapeutic duplication, **overlapping** pain score, or broad indication will be assigned a ranking order (e.g. 1st line, 2nd line, 3rd line) based on route of administration and whether it is a narcotic or non-narcotic in the following sequence:
Exclude PACU/Surgery orders for priority rankings

a) Non-narcotics will have priority ranking over narcotics.

- Example: Orders written for "Tylenol 650mg PO q4h prn mild pain" and "Norco 1 tab PO q4h prn mild pain." Tylenol will be 1st line and Norco will be 2nd line

b) Oral medications will have priority ranking over IV medications regardless of potency. Add a note to the IV medication to use IV when NPO or if failed PO

- Example: Pain medications written for "Norco 1 tab PO q4h prn severe pain" and "Dilaudid 0.2mg IV q2h prn severe pain." Norco will be 1st line and Dilaudid will be 2nd line.
- Example: MD ordered PO and IV prochlorperazine, PO is 1st line and IV is used 2nd line when pt NPO or if failed PO

c) Oral and IV medications will have priority ranking over suppositories; suppositories will have priority ranking over enemas

- Example: Orders written for "Senna 2 tabs PO qhs prn constipation," "Bisacodyl 10mg suppository PR qhs prn constipation," and "Mineral Oil PR qhs prn constipation." Senna will be 1st line , Bisacodyl will be 2nd line, andMineral Oil will be 3rd line.
- Example: MD ordered PO, IV and PR prochlorperazine, PO is 1st line and IV is 2nd line used when pt NPO or if failed PO and PR is 3rd line

d) Over the counter (OTC) medications will have priority ranking over prescription medications.

- Example: Orders written for "Lomotil 1 tab PO TID prn diarrhea" and "Loperamide 2mg QID prn diarrhea." Loperamide will be 1st line and Lomotil will be 2nd line.

e) Assign higher ranking to therapies prescribed first when there is overlapping indications (timing rule)

- Example: Docusate order 09/30/21 2030 vs senna order 10/01/21 0140. Docusate will be 1st line and senna will be 2nd line .

Table 1: Drugs and Indications for use

Drug	Indications for Use	Ranking Orders
Acetaminophen (Tylenol®)	Pain, Headache, Fever	PO> IV > PR
Acetaminophen/Hydrocodone (Norco®), Acetaminophen/Oxycodone (Percocet®), Aspirin/Oxycodone (Percodan®), Hydromorphone (Dilaudid®), Ketorolac (Toradol®), Meperidine (Demerol®), Morphine, Tramadol	Pain	OTC > Non-narcotic > Narcotic Then PO > IV Then Timing
Albuterol, Atrovent, Levalbuterol (Xopenex®), or combination	Wheezing, shortness of breath (SOB)	Call Provider to clarify
Artificial Tears and ointment	Dry Eyes	Call Provider to clarify, should not be ordered together
(Atropine sulfate/diphenoxylate (Lomotil®), loperamide (Imodium®)	Diarrhea, high osteomy output	If indication is for high osteomy output, exclude from this P&P and call Provider to clarify
Aluminum hydroxide/magnesium hydroxide (Maalox®, Mylanta®)	Cramping, indigestion, heartburn	Call Provider to clarify, should not be ordered together
Bisacodyl (Dulcolax®), Docusate, Magnesium hydroxide (MOM), Senna, Senna/Docusate, lactulose, PEG 3350 (Miralax)	Bowel management	PO > PR and timing If those that are equivalent ranking are prescribed at the same time, call Provider to clarify
Guaifenesin (Robitussin®), Oral Antitussive Preparations	Cough	Forms without codeine > those with codeine Then Timing
Lorazepam (Ativan®), midazolam	Anxiety, agitation	PO > IV and timing Call Provider to clarify if both meds prescribed for the same indication at the same time to prioritize
Menthol (Cepacol®), phenol (chloraseptic) spray, lidocaine viscous	Sore throat	Timing
Metoclopramide (Reglan®), Ondansetron (Zofran®),	Nausea/Vomiting	PO > IV > PR And

Prochlorperazine (Compazine®), Promethazine (Phenergan®)		Timing
Nitroglycerin SL or spray	Chest Pain	Call Provider to clarify, should not need both
Oxymetazoline Nasal Spray (Afrin®), Phenylephrine Nasal Spray	Congestion	Timing
Simethicone (Mylicon®, Gaviscon®)	Flatulence	N/A
Temazepam (Restoril®), Triazolam, Zolpidem (Ambien®),1) Melatonin, Diphenhydramine,	Sleep	Melatonin > Diphenhydramine > Zolpidem > Temazepam = Triazolam if prescribed at the same time, otherwise use timing rule

REFERENCES

Title 22 CCR, section 70263 (g)
The Joint Commission 2018, MM.04.01.01

APPROVALS

Pharmacy Department	**Date: 6/2025**
System Pharmacy and Therapeutics	**Date: 6/2025**
CPC	**Date: 7/2025**
Medical Executive Committee	**Date: 7/2025**
Board of Trustees	**Date: 8/2025**

ALAMEDA HEALTH SYSTEM

MEDICATIONS: SELF-ADMINISTRATION POLICY (AHS)

Campus	AHS System	***Effective Date***	03/2018
Document Owner	Medication Safety Officer	***Date Revised***	2/2021, 6/2025
		Next Scheduled Review	6/2028
Executive Responsible	System Director, Pharmacy		

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POLICY

It is the policy of AHS that the self-administration of medications by patients is not allowed **unless** there is an approved protocol or signed order authorizing the self-administration. There are circumstances where it is advantageous for certain patients to self-administer their medications while under the supervision of hospital staff. This policy ensures that those medications are adequately stored between doses and that the self-administration is properly monitored.

This policy excludes self-administration of medications through an Implantable Infusion Pump.

PROCEDURE

1. Self-administration of medications must be approved by the patient's provider or care team and the patient (or caregiver) must demonstrate their competence to do so with nursing.

2. In addition to general evaluation of decision-making capacity, the staff and practitioner will perform a more specific skill assessment, including (but not limited to) the patient's:
   a. Ability to read and understand medication labels;
   b. Comprehension of the purpose, proper dosage and administration time for his or her medications;
   c. Ability to remove medications from a container and to ingest and swallow (or otherwise administer) them; and
   d. Ability to recognize risks and major adverse consequences of his or her medications.
   e. For parenteral medications, the ability to follow appropriate sterile technique in handling the medication, any associated equipment, and the administration point.

3. Any patient considered to be at risk for self-harm, or with a known or suspected history of substance abuse or diversion may be considered inappropriate to self-administer medications.

4. Medications will not be stored within patient's room. All medication must be stored in medication rooms, carts and/or automatic dispensing machines as deemed appropriate by pharmacy and nursing staff. All medications will be provided to the patient by the nurse in accordance with the medication orders. (except Medicinal Cannabis use under SB311)

5. Self-administration of medications must be observed by a nurse to ensure appropriate use.
   a. Nursing will document medication administration in the Medication Administration Record as administered by other after self-administration is observed.
   b. Nursing will correct any inappropriate administration techniques.

6. Effects of medications must be documented in the usual manner.

7. Ongoing appropriateness of self-administration will be assessed on a continual basis. If at any time, nursing staff question the ability of the resident to safely self-administer medications, he or she will convey this concern to the attending physician immediately for re-evaluation.
   a. For SNF, assessment for appropriateness will be at least quarterly during the patient's quarterly care conference and more often if a change in the patient is identified.

REFERENCES

1. 42 CFR483.10 (n)

2. TJC MM 06.01.03 EP 2

APPROVALS

		System	Alameda
Pharmacy Department	**Date:**	6/2025	
Pharmacy and Therapeutics (P&T)	**Date:**	6/2025	
Clinical Practice Council (CPC)	**Date:**	7/2025	
Medical Executive Committee	**Date:**	7/2025	
Board of Trustees	**Date:**	8/2025	

ALAMEDA HEALTH SYSTEM	Policy	
	MEDICATION CARTS, KITS AND TRANSPORT BOXES FOR SPECIFIC DEPTS. AND DIVISIONS	**29923 1**
	LEVEL ☐ System ☐ Site	EFFECTIVE DATE: 6/2025

Policy

To provide access and storage to medications in boxes or kits to specific areas where Automated Dispensing Machines (ADM, e.g. Pyxis) are not accessible and/or certain specific drugs are not included in crash carts. These departments/divisions may include however not limited to Allergy Clinic, Anesthesiology, Cardiology, Diagnostics, Oral Surgery, Operating Room, Emergency Department, and Radiology.

Other medication kits are assembled and put in ADM by pharmacy for the ease of removal under specific situations.

Procedures

A. Preparation

1. Pharmacy staff fills medications listed in the boxes and kits. Non-medicinal supplies in oral surgery boxes are filled by the Oral Surgery division.
2. Pharmacy staff records expiration dates of mediations on the content list.
3. Pharmacy staff who prepares the box or kit will sign and date on the content list.
4. Pharmacist will check all medications against the content list for correct quantity and expiration.
5. Pharmacist will sign and date the content list after checking the box or kit.
6. The signed and dated content list will be put inside the box or kit.
7. A copy of this content list can be put outside the box or kit. Or a sticker with the name of earliest expired drug and expiration date will be put outside the box or kit. This is to identify when to replace the content of the box or kit.
8. Pharmacy will put a tamper resistance lock on the checked box or kit to ensure the box or kit is secured before being dispensed.

B. Dispensing

1. When a box or kit is needed for a procedure by a department/division, the department/division staff will come to pharmacy to pick up the specific box or kit.
2. Pharmacy staff, before dispensing the box or kit, will make sure the lock is secured and medications are not expired.
3. Pharmacy staff fills out the dispensing log to indicate when and where the box/kit is dispensed.

C. Storage

1. Each department/division is responsible for storing the box/kit in an area where direct supervision of its usage is allowed until the procedure is complete.
2. Anesthesia department, oral surgery division and radiology department will store the boxes/kits in their areas until replacement.
3. Such storage areas should be easily monitored by the department or division staff to prevent unauthorized usage.

D. Administering and Returning
   1. When a medication is needed, the department staff will break the lock to open the box or kit.
   2. The department/division staff will put the patient addressograph sticker on the content list for subsequent billing by pharmacy.
   3. The department/division staff will return the used box or kit with the patient stamped content list to pharmacy for replacement.
   4. In the situation where the lock is found broken in the department/division, but medications are not used, the box or kit should be returned to pharmacy for checking.

E. Replacement
   1. Pharmacy will follow the procedures under "Preparation" in this policy to replace and refill any medications used in the box or kit that is returned from the department/division.

F. Medication kits stored in Automated Dispensing Machine (ADM, e.g. Pyxis)
   1. These kits are assembled in pharmacy and checked by pharmacist before putting in ADM.
   2. Kits are removed from ADM according to the ADM procedure.
   3. A refill or stock out report will be printed in the pharmacy to prompt for replacement.
   4. Used kits should be placed in the "return to pharmacy" bin for pick up and return to pharmacy.

APPROVALS

		System	Alameda	AHS/Highland/John George/San Leandro
Pharmacy and Therapeutics (P&T)	**Date:**	6/2025		
Clinical Practice Council (CPC)	**Date:**	7/2025		
Medical Executive Committee	**Date:**	7/2025		
Board of Trustees	**Date:**	8/2025		

ALL Acute Care Medication Carts and Kits

Department/Divisions	Name of Emergency Box/Kit	Page
Radiology	Radiology Contrast Allergic Reaction Kit	3
Critical Care	RSI kit	3
Employee Health Kit	Adult Anaphylaxis Kit	4
Anesthesia	Anesthesia Support Kit	

Radiology Contrast Allergic Reaction Kit

Medication	Quantity	Expiration
Diphenhydramine Inj. 50 mg/ml 1 ml Vial	1	
Epinephrine Inj. 1 mg/ml (1:1000) 1 ml Vial (in light protection bags)	2	
Methylprednisolone Inj.125 mg Vial	1	

Epinephrine Dosing: Hypersensitivity Reaction (e.g. anaphylaxis):
IM administration in the anterolateral aspect of the middle third of the thigh is preferred in the setting of anaphylaxis. Subcutaneous administration results in slower absorption and is less reliable.

IM (preferred anterior thigh): **Adults:** 0.3 to 0.5 mg (0.3 to 0.5 ml) of 1 mg/ml solution every 5 to 15 minutes. **Peds:** 0.01 mg/kg (Max 0.3 mg) of 1 mg/ml solution (AAAAI [Lieberman 2015]; AHA [Vanden Hoek 2010]; WAO [Kemp 2008])

Rapid Sequence Intubation (RSI) Kit

Quantity	Medication	Expiration
1	Etomidate 2 mg/ml vial (total 10 mL)	
1	Rocuronium 10 mg/ml vial (total 10 mL)	
2	Succinylcholine 20 mg/ml inj (total 10 mL)	

Employee Health Adult Anaphylaxis Kit

Quantity	Medication	Expiration date
2	Diphenhydraime 25mg caps	
1	EpiPen 0.3mg/0.3mL prefilled syringe	
1	BD syringe, Leur-lok (1 ml syringe)	
1	BD Eclipse 25G needle	
2	Isopropyl alcohol 70% prep pads	

Anesthesia Support Kit

Quantity	Medication	Expiration
1	Ephedrine 50 mg/ml (1 ml) vial/ampule	
1	Etomidate 2 mg/ml (10 ml) vial	
1	Norepinephrine 1 mg/ml (4 ml) ampule	
1	Propofol 10 mg/ml (20 ml) vial	
1	Rocuronium 10 mg/ml (10 ml) vial	
1	Succinylcholine 20 mg/ml (5 ml) syringe	

Back up medications for situations like power outage and Pyxis failure. The kit is stored in a locked box.

Wilma Chan Highland Hospital Medication Carts and Kits

Anesthesia Intubation Kit (to be put in Anesthesia Airway Backpack)

Drug	Quantity	Expiration
Atropine Inj. 0.1 mg/ml 10 ml syringe	1	
Epinephrine Inj. 0.1 mg/ml (1:10,000) 10 ml syringe	1	
Etomidate Inj. 2 mg/ml 10 ml vial	1	
Phenylephrine Inj. 100 mcg/ml 10 ml syringe	1	
Propofol Inj. 10 mg/ml 20 ml vial	2	
Rocuronium Inj. 10 mg/ml 10 ml vial	1	
Succinylcholine Inj. 20 mg/ml 5 ml syringe	1	
Sugammadex 100 mg/ml 5 ml vials	3	

Cardiac CT Scan/Nuclear Medicine Box

Drug	Quantity	Expiration
Albuterol Inhaler 90 mcg/puff 8 gm inhaler	1	
Aminophylline Inj. 25mg/ml 10 ml vial	2	
Caffeine inj 60mg/3mL	1	

Electrocardiography (EKG) Kit

Medication	Strength	Quantity	Expiration
Atropine inj	1mg/1mL Vial	1	
Diphenhydramine inj.	50 mg/1 ml Vial	1	
Metoprolol inj.	5 mg/5 ml Vial	1	
Nitroglycerin SL tablet	0.4 mg	2 bottles (25 tabs/bottle)	

HEART ALERT (STEMI) Kit

(STEMI = ST-Elevation Myocardial Infarction)

Medication Name	Dose Given	Time	Route	Documented in MAR	Quantity in Kit	Exp. Date	Quantity Used
Atropine Inj 1mg (0.1 mg/ml) 10 ml prefilled syringe				☐	1		
Epinephrine Inj 1mg (1:10,000) 10 ml prefilled syringe				☐	1		
Amiodarone Inj 150mg (50mg/ml) 3 ml vial				☐	2		
Diphenhydramine Inj 50mg/ml 1 ml vial				☐	1		
Nitroglycerin 0.4 mg sublingual tablets				☐	1 bottle		

ADULT TRANSPORT/CODE BOX

Generic drug name	Quantity
Atropine 1mg/10mL syringe	1
Dextrose 50% 25g/50mL syringe	1
Dextrose 10% 100mg/mL (250mL bag)	1
Epinephrine 1:10000 1mg/10mL syringe	1
Oral glucose gel 15g	1
Normal saline 10mL flush	3
Angiocath starter kit*	1
Empty syringe 3mL	1
Empty syringe 10mL	3
18 gauge eclipse needle	4
25 gauge eclipse needle for IM inj	1

Generic drug name	Quantity
RSI meds grouped together	
Etomidate 2mg/mL (10mL)	1
Rocuronium 10mg/mL (10mL)	2
Succinylcholine 20mg/mL (5 ml) syringe	2
Midazolam 10mg/2mL (Versed)	1
Naloxone 2mg/2mL syr	1

*20G 1 ¼" Catheter x2, 18G 1 ¼" catheter x2, IV starter kit with ChloraPrep (DYND74260) x2

*20G 1 ¼" Catheter x2, 18G 1 ¼" catheter x2, IV starter kit with ChloraPrep (DYND74260) x2

Neonatal Transport Box- Pharmacy Section

Pharmacy Section ONLY

Epinephrine 1:10,000 (0.1 mg/mL) 10mL Syringe- 1 ea____ (√)

(Dose of Epinephrine= 0.1 to 0.3 mL/KG of Epinephrine 1:10,000 IV)

Pharmacist Code Stroke Kit

Quantity	Medication	Expiration Date
2	30mL syringe	
2	10mL syringe	
5	5mL syringe	
1	BD Alaris Pump Infusion Set (REF 2426-0500)	
6	18G Eclipse Needles	
6	Saline Flush 10mL	
1	Nicardipine 25mg in 100mL (either NS or D5)	
1	Tenecteplase 50mg kit	
1	Labetalol hydrochloride 100mg / 20mL vial	
N/A	Miscellaneous: labels, tapes, and dosing sheet	

Non-Cytotoxic Vesicant Medication and Fluids Extravasation Kit

Quantity	Medications	Expiration Dates
2	Phentolamine mesylate for injection 5 mg/vial	
2	Hyaluronidase (Amphadase®) 150 units/ml, 1 ml vial (Hyaluronidase is STORED IN PYXIS REFRIGERATOR)	
2	0.9% Sodium chloride for injection, preservative free, 10 ml	
3	Nitroglycerin Ointment USP, 2% (NITRO-BID®) 1 inch (1 gram) foilpac®	

Operation OB – MEDICATION BOX

Quantity	Drug	Expiration Date
2	Oxytocin (Pitocin) 10 units/ml 1 ml vial	
5	Misoprostol (Cytotec) 100 mcg tablet	

OB Procedure Cart

Nursing:
Stamp with patient's name, place in medication box and return to pharmacy

Quantity	Medication	Expiration
2	Calcium gluconate 1g vials	
1	Hydralazine 20mg/mL vial	
1	Labetalol100mg/20mL (5mg/mL) vial	
1	Magnesium sulfate 20g/500mL bag	
2	Magnesium sulfate 50%, 5gm/10mL, 10mL vials	
5	Misoprostol 200mcg tab	
1	Naloxone 2mg/2mL syringe	
1	Nitroglycerin spray 0.4mg/spray	
2	Oxytocin 30 units/500mL bag	
4	Oxytocin 10 units/mL, 1mL vial	
3	Nifedipine 10mg, Immediate Release tabs	
1	Terbutaline1mg/mL vial	
1	Tranexamic Acid 1000mg/10ml	

The following medications are in the **9W** Pyxis Refrigerator under "**OB PPH Emergency Kit**", to access:

- Log in to pyxis
- Hit "remove meds" button
- Hit "kit" button at the bottom of the screen
- Choose the "**OB PPH Emergency Kit**"
- Remove the below meds

Pyxis items in the OB Code Kit	
Quantity	**Medication**
1	Hemabate 250mcg ampule (refrigerator in zip-lock bag)
2	Methergine 0.2mg/mL ampule (refrigerator in zip-lock bag)
5	Misoprostol 200mcg tab

****Diazepam inj** must be **removed separately from Pyxis** when needed

Oral Surgery Box

Supplies	Qty.
Alcohol Pads	8
BD 10ml Syringe w/ Luer Lock Tip Blunt Fill Needles	2
BD 5 ml Syringe	3
BD Eclipse 18G x1½" Needles	4
BD Eclipse 3 ml Syringe w/ 21G x1½" Needle	3
CPR Mask	1
Extension Set w/ y-site	1
IV Catheter 18G x1¼"	2
IV Catheter 20G x1¼"	2
IV Catheter 22G x1"	2
IV Start Kit w/Chloral Prep	2
Oxygen Mask	1
Regular IV Set	1

Drugs	Qty.	Expiration Date
Albuterol Inhaler	1	
Aspirin 325mg	2	
Atropine Inj. 0.4 mg/ml 1 ml Vial	2	
Dextrose 50% Inj. 0.5 gm/ml 50 ml Syringe	1	
Diphenhydramine Inj. 50 mg/ml 1 ml Vial	1	
Ephedrine Inj. 50 mg/ml 1 ml Ampule w/ Filter needle	1	
Epinephrine 1:1000 Inj. 1 mg/ml 1 ml Ampule (For anaphylaxis: Adults: 0.3 to 0.5 mg (0.3 to 0.5 ml) of 1 mg/ml solution given IM, preferred anterior thigh)	1	
Esmolol 100mg/10ml	1	
Flumazenil Inj. 0.1 mg/ml 5 ml Vial	1	
Hydralazine 20mg/mL (1mL) vial	1	
Labetalol Inj. 5 mg/ml 20 ml vial	1	
Lidocaine Gel 2% 5 ml Tube	1	
Methylprednisolone Inj. 125 mg Vial	1	
Naloxone Inj. 0.4 mg/ml 1 ml Vial	2	
Nitroglycerin SL Tablet 0.4 mg/tab #25 tab Bottle	1	
Normal saline 10ml vial	2	
Normal Saline 250 ml Bag	1	
RSI Kit	1	
Sterile Water Inj. 10 ml Vial	1	

Drugs are replaced by pharmacy. Supplies are replaced by dental dept. oral surgery staff

Hypersensitivity Reaction Kit for Infusion Center

Medication	Quantity	Expiration
Diphenhydramine Inj. 50 mg/ml 1 ml Vial	1	
Methylprednisolone Inj.125 mg Vial	1	
Epinephrine 1mg/mL vial (Refer to "MANAGEMENT OF ACUTE ADVERSE REACTIONS (ADR) POLICY: CHEMOTHERAPY/BIOTHERAPY/IMMUNOTHERAPY: policy for dosing)	1	

Famotidine inj. 20 mg/2ml vials are in Pyxis Refrigerator.

- Atropine vial and/or syringe are in the pyxis machine
- Kit will include one 3mL syringe, one 18-gauge needle and one 21-gauge needle.

Chemotherapy/Biotherapy Extravasation Kit

Quantity	Medication	Expiration Date
1	Sodium Thiosulfate 25% (12.5gm/50mL)	
1	Hyaluronidase 150 units/1ml vial **stored in fridge** (Alameda Hospital refrigerator located in the OR/surgery department pyxis)	
1	Topical DMSO 50% - 50 ml vial	
2	Dexrazoxane 500mg vial (Highland Campus Only)	
2	50mL Sterile Water (Highland Campus Only)	

ED Block Cart

Quantity	Medication
Rescue/LAST Treatment	
12	Preferred choice: Intralipid (Fat Emulsion) 20% inj 200 - 250 ml bag with 1.2 micron filter tubing OR 2nd choice: SMOFlipid 20% - 100mL bags x2 with 1.2micron filter tubing + ASRA checklist for treatment of local anesthetic systemic toxicity (LAST) [both original and simplified versions]
2	16 gauge needles
2	50mL syringes

ED Code Bag

Generic drug name	Quantity
Atropine 1mg/10mL syringe	1
Dextrose 50% 25g/50mL syringe	1
Dextrose 10% 100mg/mL (250mL bag) **during D50W shortage only**	1
Epinephrine 1:10000 1mg/10mL syringe	1
Etomidate 2mg/mL (10mL)	1
Glucose gel (oral) 15g	1
Midazolam 10mg/2mL (Versed)	1
Naloxone 2mg/2mL syr	1
Rocuronium 10mg/mL (10mL)	2
Succinylcholine 20mg/mL (5 ml) syringe	2
Tenecteplase kit	1
Supplies	**Quantity**
Normal saline 10mL flush	4
Angiocath starter kit*	1
Empty syringe 3mL	2
Empty syringe 10mL	2
18 gauge eclipse needle	4
25 gauge eclipse needle for IM inj	1

Alameda Hospital Only Medication Carts and Kits

Department/Divisions	Name of Emergency Box/Kit	Page
Critical Care	• Anaphylaxis Kit • CCU Difficult Airway Cart	13 14
Critical Care/ED	• Kcentra kit • TNKase kit	15 15
Misc.	• Pain Medication Tray	16

ANAPHYLAXIS KIT

KEEP AT BEDSIDE FOR PACLITAXEL (TAXOL), L-ASPARAGINASE, PEPASPARAGINE INJECTION

PATIENT NAME
RN NAME

Quantity	Generic Name	Trade Name	Strength	Size	Form
1	Diphenhydramine	Benadryl	50mg/ml	1ml	SDV
1	Epinephrine (1:1000) (For anaphylaxis: Adults: 0.3 to 0.5 mg (0.3 to 0.5 ml) of 1 mg/ml solution given IM, preferred anterior thigh)	Adrenalin	1mg/ml	1ml	Ampule
1	Filter Needle			19G	Needle
1	Methylprednisolone	Solu-Medrol	125mg/2ml	2ml	SDV
1	Albuterol Solution	Proventil	2.5mg/3ml	3ml	SDV
3	Syringe			3ml	Syringe
3	Needle 18G			18G	Needle
3	Alcohol Prep Pad			Each	Pad

RETURN TO PHARMACY AFTER INFUSION.

FIRST EXPIRING DRUG:	**EXPIRATION DATE:**

TECH/RPH	**/**

CCU Difficult Airway Cart Drug List

Patient Addressograph

Drugs	Quantity	Quantity Used
Lidocaine 2% Jelly 30ml	2	
Lidocaine 2% 50 ml Multiple Dose Vial	1	
Hurricaine Topical Spray	1	
Phenylephrine Nasal Decongestant Spray	1	

First Drug(s) to Expire:_____ Expiration Date:_____

Filled/Checked By:_____/_____ Date:_____

***Return entire kit to pharmacy for replacement after each use**

Kcentra® Kit Content

(Prothrombin Complex Concentrate, 4 Factor Unactivated)

Item Name	Quantity	Expiration Date
Kcentra Reconstitution Instructions	1	x
Orange "Medication Added" sticker	6	x
60 mL luer lok syringe	2	x
20 mL luer lok syringe	4	x
16 gauge needles	6	x
Empty 100mL IVPB bags	6	
Alcohol swabs	10	x
Kcentra 1000 unit manufacturer box	4	
Kcentra 500 unit manufacturer box	2	

Filled by: _____ Checked by: _____ Date checked: _____

Lock Number: _____

Date Used: _____

PATIENT HOSPITAL LABEL STICKER

***Return entire kit to pharmacy for replacement after each use**

TNKase® Kit Content

Item Name	Quantity	Expiration Date
TNKase 50mg	1	
AIS bag: dose chart, Orange "Medication Added" sticker, 5cc luer lok syringe, AIS flyer	1	
STEMI bag: dose chart, Orange "Medication Added" sticker, STEMI flyer	1	x

Filled by: _____ Checked by: _____ Date checked: _____

Lock Number: _____ Kit #: _____

NURSE: Return to Pharmacy when used

NURSE:

Place Patient Hospital Sticker

Pain Medications Tray List

Drugs	Exp Date	QTY	QTY Used
Lidocaine 1% P.F. (10 mg/mL) – 5 mL		25	
Lidocaine 2% P.F. (20 mg/mL) – 5 mL		10	
Bupivacaine 0.25% P.F. (2.5 mg/mL) – 10 mL		10	
Dexamethasone P.F. 10 mg/mL – 1 mL		25	
Kenalog (Triamcinolone Acetonide) 40 mg/mL – 1 mL		12	
Bupivacaine 0.5% P.F. (5 mg/mL) – 30 mL		9	
MethylPREDNISolone acetatae injectable suspension (Depo-medrol) 80mg		4	

San Leandro Only Medication Carts and Kits

Cardiology Drug Kit

Cardiology Drug Kit	Aminophylline 500mg vial	1
Cardiology Drug Kit	Atropine 1mg/10ml	1
Cardiology Drug Kit	Esmolol 100mg/10ml	1
Cardiology Drug Kit	Nitroglycerin 0.4mg tabs	25
Cardiology Drug Kit	Verapamil 5mg/2ml	1
Cardiology Drug Kit	22ga x1.5” safety needle	1
Cardiology Drug Kit	Diltiazem 5mg/ml 10 ml vial	1

Dobutamine Stress Test Kit (prepared upon order)

Dobutamine stress test kit (prepared upon order)	Dobutamine 250mg/d50w 250ml
Dobutamine stress test kit (prepared upon order)	d5w 500ml
Dobutamine stress test kit (prepared upon order)	esomolol 100mg/10ml
Dobutamine stress test kit (prepared upon order)	atropine 1mg/10ml inj

Rapid Response Kit

Rapid Response Kit	Ipatroprium/Albuterol 0.5mg/3mg amp	1
Rapid Response Kit	Nitroglycerin 0.4mg	1
Rapid Response Kit	Aspirin 325mg tab	1
Rapid Response Kit	Dextrose 50% 50ml	1
Rapid Response Kit	Naloxone 0.4mg	1
Rapid Response Kit	NS 1000ml IV	1

Ancillary ICU Code Box

Ancillary ICU Code Box	Amiodarone 150mg/3ml inj.	3
Ancillary ICU Code Box	Dextrose 5% 100ml bag	1
Ancillary ICU Code Box	Filter - 0.2 Micron	1
Ancillary ICU Code Box	Adenosine 6mg/2ml inj	3
Ancillary ICU Code Box	Atropine 1mg/10ml syringe	3
Ancillary ICU Code Box	Calcium Chloride 10% syringe	1
Ancillary ICU Code Box	Dextrose 50% 50ml syringe	1
Ancillary ICU Code Box	Dopamine 800mg/250ml D5W IV drip	1
Ancillary ICU Code Box	Epinephrine 1mg/10ml syringe	4
Ancillary ICU Code Box	Lidocaine 0.4% 250ml IV drip	1
Ancillary ICU Code Box	Lidocaine 100mg syringe	2
Ancillary ICU Code Box	Magnesium 1gm/2ml vial (Dilute with 9ml NS)	2
Ancillary ICU Code Box	Naloxone 2mg/2ml syringe	2
Ancillary ICU Code Box	Sodium Bicarbonate 8.4% syringe	2
Ancillary ICU Code Box	Sodium chloride flush 10ml syringe	4
Ancillary ICU Code Box	Sterile water 10ml	2
Ancillary ICU Code Box	Vasopressin 20 units/1 ml inj.	2

Kcentra® Kit Content

(Prothrombin Complex Concentrate, 4 Factor Unactivated)

Item Name	Quantity	Expiration Date
Kcentra Reconstitution Instructions	1	x
Orange "Medication Added" sticker	6	x
60 mL luer lok syringe	2	x
20 mL luer lok syringe	4	x
16 gauge needles	6	x
Empty 100mL IVPB bags	6	
Alcohol swabs	10	x
Kcentra 1000 unit manufacturer box	4	
Kcentra 500 unit manufacturer box	2	

Filled by: _____ Checked by: _____ Date checked: _____

Lock Number: _____

Date Used: _____

PATIENT HOSPITAL LABEL STICKER

TNKase® Kit Content

Item Name	Quantity	Expiration Date
TNKase 50mg	1	
AIS bag: dose chart, Orange "Medication Added" sticker, 5cc luer lok syringe, AIS flyer	1	
STEMI bag: dose chart, Orange "Medication Added" sticker, STEMI flyer	1	x

Filled by: _____ Checked by: _____ Date checked: _____

Lock Number: _____ Kit #: _____

NURSE: Return to Pharmacy when used

NURSE:

Place Patient Hospital Sticker

SLH OR Eye Medication Tray 1 Drug List

Drugs	Exp Date	QTY	QTY Used
Cyclopentolate (Cyclogyl) Soln 2% - 2 mL		1	
Cyclopentolate (Cyclogyl) Soln 1% - 2 mL		1	
Tropicamide 1% - 3 mL		1	
Phenylephrine (AK-Dilate) Soln 10% - 5 mL		2	
Sulfacet/Pred (Blephamide) Oint 3.5gm		1	
Gentamicin Soln 5 mL		2	
Gentamicin Oint 3.5 gm		1	
Erythromycin Oint 3.5 gm		2	
Ciprofloxacin (Cipro) Soln 0.3% - 2.5 mL		1	
Neo/Poly B/Dex (Maxitrol) Oint 3.5 gm		10	
Atropine Soln 1% - 2 mL		2	
Epinephrine PF Soln amp 1% - 2 mL		2	
Lidocaine PF Injection amp 1% - 2mL		10	
Cefazolin Injection Vial 1 gm		3	
Sterile Water for Injection SDV 10 mL		3	
Atropine Oint 1% - 3.5 gm		2	
Homatropine Soln 5% - 5 mL		2	
Lidocaine PF Injection 4% - 5 mL		6	
Gentamicin Injection SDV 80 mg/2mL		6	
Dexamethasone Injection SDV 4 mg/mL		8	

SLH OR Eye Medication Tray 2 Drug List

Drugs	Exp Date	QTY	QTY Used
Timolol Soln 0.5% - 5 mL		2	
Lidocaine/Epi Injection SDV 2%/1:200K – 20 mL		1	
Tetracaine Sterile Soln 0.5% - 2 mL		2	
Liquifresh PM Oint 3.5 gm		2	
Brinzolamide (Azopt) 1% - 10 mL		6	
Prednisolone (Pred-Forte) Soln 1% - 5 mL		3	
Fluorescein Sodium Ophth Strip 0.6 mg		3	
Lidocaine/Epi Injection SDV 1%/1:100K – 20 mL MDV		1	
Acetylcholine (Miochol-E) Soln – 2mL		3	
Trypan Blue (Vision Blue) Soln Syr 0.06% - 0.5 mL		5	
Pilocarpine Sterile Soln 2% - 15 mL		2	
Tetracaine Soln 0.5% - 15 mL		2	
Bupivacaine 0.75% - 10 mL		6	
Lidocaine Inj MDV 2% - 5 mL		6	
Lidocaine 2% - 50 mL		1	
Tetracaine (TetraVisc) Soln 0.5% - 5 mL		6	
Gatifloxacin (Zymaxid) Soln 0.5% - 2.5 mL		8	

OR Bleeding Kit

OR Bleeding Kit	GELFOAM (SIZE 100)	2
OR Bleeding Kit	Recothrom (5000 units)	4
OR Bleeding Kit	HEPARIN (1,000 UNITS/ ML) 10 ML	3
OR Bleeding Kit	HEPARIN (1,000 UNITS/ ML) 30 ML	1
OR Bleeding Kit	Gentamicin (80 MG/ 2 ML) 2 ML	4
OR Bleeding Kit	PROTAMINE (10 MG/ ML) 5 ML	1
OR Bleeding Kit	Visipaque (320mg/ml) 50ml	3
OR Bleeding Kit	30 ML SYRINGE	1
OR Bleeding Kit	18 GA HYPO NEEDLE	1
OR Bleeding Kit	MED LABELS	2

Radiology Emergency Drug (CT-box)

Radiology Emergency Drug (CT-Box)	Syringe w/ needle 3ml	3
Radiology Emergency Drug (CT-Box)	Atropine 1mg/ml vial	1
Radiology Emergency Drug (CT-Box)	Benadryl 50mg/ml vial	1
Radiology Emergency Drug (CT-Box)	Epinephrine Inj. 1 mg/ml (1:1000) 1 ml Vial (For anaphylaxis: Adults: 0.3 to 0.5 mg (0.3 to 0.5 ml) of 1 mg/ml solution given IM, preferred anterior thigh)	1
Radiology Emergency Drug (CT-Box)	Ammonia Inhalants	4
Radiology Emergency Drug (CT-Box)	Benadryl 25mg cap	4

Procedure Room Drug Box

Procedure Room Drug Box	Fentanyl 100mcg/2ml	8
Procedure Room Drug Box	Midazolam 5mg/5ml	8

ALAMEDA HEALTH SYSTEM

Highland Hospital Outpatient Pharmacy Quality Assurance and Medication Error Reporting

Site	Highland Hospital Outpatient Pharmacy	***Previous Revision Dates***	
Effective Date	9/2023	***Date Revised***	05/2025
Document Owner	MGR SYS MED SAFETY-CLIN PHARM	***Next Scheduled Review***	05/2028
Executive Responsible	Please Fill In		
Approvals	BOT, QPSC		

Printed copies are for reference only. Please refer to electronic copy for the latest version.

Purpose

To provide guidelines for Outpatient Pharmacy standardized reporting of adverse medication errors and actions taken in response to these events as required by the California Board of Pharmacy (BOP).

Policy

Adverse medication events (ADE's) will be reported regularly to the Midas Safety Alert system, including medication errors, quality assurance events, or adverse events, that have reached the patient or patient's agent. Highland Hospital Outpatient Pharmacy, as part of the Alameda Health System, subscribes to a Just Culture algorithm.

Definitions

1. Just Culture- a system where honest human errors are treated as learning opportunities, rather than as reasons for punishment.

2. Adverse Events – any undesirable experience that is associated with the use of a medical product or medication, in a patient.

3. Serious disability- refers to physical or mental impairment that limits abilities in major life activities, or results in the loss of bodily functions/parts.

4. Medication Error – any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in control of the healthcare professional, patient or consumer and is determined based on the one or more of the following types of criteria:
    a. Types of Medication Error (includes but not limited to) – prescribing errors, transcribing errors, dispensing errors, and medication delivery errors, where the medication has left the pharmacy. The specifics are categorized on the following:
        i. Prescribing
            a) Contraindicated.
            b) Duplicate Drug Order, not corrected by pharmacist.
            c) Illegible/Unclear Order, not clarified by pharmacist.
            d) Drug Order not authorized by prescriber.

e) Inappropriate Order / Altered Order, not corrected by pharmacist.
f) Incomplete Order, not clarified by pharmacist.
g) Miscalculated Order, not clarified by pharmacist.

ii. Transcribing:
a) Transcribing (copying) error.
b) Order typed or entered incorrectly.
c) Verbal Order (V.O.) written incorrectly.
d) Wrong patient.
e) Labeling error.

iii. Dispensing
a) Contraindicated.
b) Incorrect dose.
c) Failed to verify order.
d) Improper preparation/compounding.
e) Miscalculated dose.
f) Mislabeled, packaging and nomenclature.
g) Incorrect drug.
h) Wrong patient.
i) Drug order not authorized by prescriber.
j) Incorrect route of administration.
k) Wrong directions.

Procedure

1. If an adverse medication event (ADE) is identified that has reached the patient or has the significant potential to cause harm, a Quality Assurance-electronic occurrence report must be completed via the Midas- Safety Alert system as soon as discovered.
    a. An investigation of each medication error shall start as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered.

2. Midas Safety Alert report should contain:
    a. The date, location, and participants in the quality assurance review.
    b. The pertinent data and other information relating to the medication error(s).
    c. The review and documentation of any patient contacted, as required.
    d. The findings and determinations generated by the quality assurance review.
    e. Recommended changes to pharmacy policy, procedure, systems, or processes, if any.

3. The Pharmacy Director, Manager, PIC, or designee shall review these documents for completeness and accuracy (i.e. ensuring that the parameters of the event completed by the employee are correct).

4. The Pharmacy Director, Manager, PIC, or designee will take appropriate action as applicable and document such actions in the Midas Safety Alert report.

5. The Pharmacy Director, Medication Safety Officer, Pharmacy Manager, and PIC have access to medication errors and adverse drug reactions that have been entered into the Midas Safety Alert system, via a manager's worklist.

6. The record of quality assurance review must be easily retrievable in the pharmacy for at least 3 years from the date the record was created. Records will be retrievable via the Midas Safety Alert reporting system.

7. Data collected via the Midas reporting system shall be reviewed by the Medication Error Reduction Team (MERT). Review of medication events for tracking and trending to assess improvements in errors with mitigation strategies in place. The review shall occur at least quarterly.

8. MERT, Pharmacy Manager or PIC shall determine appropriate follow-up actions that are needed to reduce the likelihood of similar errors in the future. Recommendations may include:

    a. Use of continuous quality improvement principles to improve medication use processes and outcomes.
    b. Referral to appropriate Peer Review Committees.
    c. Staff education efforts.
    d. IT/Epic system improvements and safeguards.

9. Resolutions and methods of prevention will be reviewed with staff (staff huddles, individual review or email) and may be added to the standard operating procedure manual, along with providing individualized trainings, as needed.

10. Errors reported by Pharmacy or Patient
    a. The pharmacy will communicate with the patient or patient's agent and prescriber, when a medication error has occurred, and steps required to avoid or mitigate the error.
    b. When a medication error has occurred (drug was administered to or by the patient or resulted in clinically significant delay in therapy) the pharmacy will communicate to the prescriber that a medication error has occurred.

11. Reporting errors from automated dispensing systems
    a. Highland Outpatient Pharmacy operates an unlicensed automated drug delivery system (ScriptPro) within the premises of the pharmacy.
    b. Any complaint, error, or omission involving the automated dispensing system (ScripPro) shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.
    c. Quality Assurance events related to the ScriptPro must be reported to the California Board of Pharmacy at the time of annual renewal of the pharmacy license.

12. Reporting errors related to compounds
    a. In the event of an error, not being limited to an instance where there is a negative patient outcome, Midas Safety Alert will be completed using the AHS Standard Midas Reporting tool.
    b. If the error involves a compounded medication, the individual involved will undergo appropriate training or, at minimum, document review of the policies and procedures.
    c. In the event where a negative patient outcome is associated with a compound, pharmacy will also report to MedWatch within 72 hours of being advised.
        i. The prescriber will be notified within 72 hours of the pharmacy being advised.
13. Medication errors under AB 1286, reporting by Pharmacy
    a. In addition to the steps outlined above, Highland Outpatient Pharmacy is required to report medication errors under AB 1286, to California Board of Pharmacy or the Board Approved vendor Institution for Safe Medication Practices (ISMP), within 14 days of discovery.
        i. Reportable medication errors include:

1. Wrong drug
2. Wrong patient
3. Wrong directions
4. Wrong preparations
5. Wrong route of administration
6. Any variation from a prescription drug order not authorized by prescriber. Errors corrected prior to dispensing to patient or patient's agent are not required to be reported to ISMP or CA BOP, unless they meet other requirements noted within this policy.

ii. An outpatient hospital pharmacy shall not be required to report a medication error that meets the requirements of an adverse event that has been reported to the California Department of Public Health pursuant to Section 1279.1 of the Health and Safety Code.
    1. A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected.
        a. Product or device events:
            i. Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product.
        b. Care management events:
            i. A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.

b. Business and Professions Code §4113.1 requires that pharmacy maintain records demonstrating compliance with AB1286- error reporting, for 3 years.
c. Records must be immediately available to California Board of Pharmacy inspector(s).

References

1. California Code of Regulations, Article 12, Section 1711
3. California Code, Business and Professional Code - BPC 4125
4. California Code, Business and Professions Code- BPC 4113
5. California Health and Safety Code- HSC 1279.1

APPROVALS

		System	**HH/SLH/JG/FM**

Regulatory Department	**Date:**	**6/2025**	
Pharmacy Departmental	**Date:**		**6/2025**
System Pharmacy and Therapeutics	**Date:**	**6/2025**	
CPC	**Date:**	**7/2025**	
Medical Executive Committee	**Date:**	**7/2025**	
Board of Trustees	**Date:**	**8/2025**	

Alameda Health System
Clinical Practice Council Charter

Purpose of the Clinical Practice Council

The Clinical Practice Council (CPC) is under the governance of the Alameda Health System (AHS) Medical Staff. The primary purpose of the Alameda Health System (AHS) Clinical Practice Council (CPC) is to review and approve all organization or clinical policies, cross-department protocols, and plans that impact or affect the delivery of patient care. In addition, CPC will review department-level procedures and guidelines.

Guiding Principles

- Ensure all policies, procedures, guidelines, protocols, and plans within CPC's scope:
  - are evidence-based and align with the best patient care and highest safety standards;
  - reflect consensus-driven patient care across disciplines and departments; and
  - are easily accessible to all employees.
- Support continuous performance improvement and patient safety throughout the Alameda Health System.

Approval Responsibilities & Reporting Structure

- All policies, procedures, guidelines, cross-department protocols, and plans that impact or affect the delivery of patient care will be reviewed in their respective committee prior to submission to CPC for review.
- CPC will review all submissions based on its guiding principles. Policies, protocols, and plans approved by CPC will be sent to the medical executive committee (MEC) for approval.
  - MEC will approve or reject documents submitted by CPC.
  - All documents approved by MEC will be presented to the BOT for final approval.
- CPC will review and provide guidance on department procedures and guidelines
- CPC oversees PolicyTech, which is supported by the quality department via the Policy Coordinator(s).

Review and Appeals Process

- If the MEC rejects or requests changes to a document, the policy coordinator will notify the author and provide feedback from the MEC.
- The revised document will be submitted for secondary review and approval by the next CPC meeting; if unable to meet deadline, the author will provide updates to the CPC chair(s).
- Unresolved disputes and delays should be escalated to the CPC chair who can coordinate resolution.
- Timely review and needed collaboration are expected.
- Efforts will be made at each meeting to move pending documents forward.

Membership Composition

- The Clinical Practice Council is a multidisciplinary committee consisting of members from the medical staff, quality, nursing, pharmacy, informatics, infection control, and other members as deemed necessary and appropriate to fulfill its function. Please see the table for committee membership.
- Committee members are appointed by the Chief of Staff (COS); co-chairs are appointed in consultation with the Chief Medical Officer (CMO) and the Chief Clinical Officer (CCO).
- Members serve a minimum of four years with staggered end dates.
- Members must attend at least 75% of scheduled meetings annually.
- Inactive members (failing to meet attendance requirements) will be replaced to maintain continuity.
- A proxy may vote only when attending in an official capacity for a designated member.

Clinical Practice Council Meetings

- CPC meets monthly.
- Meeting minutes are recorded, disseminated, and stored per regulatory requirements and AHS policy.
- The meeting agenda and materials are emailed to all active members at least five days before the meeting.
- A quorum consists of at least 30% active committee members. At least 3 physicians and 3 nurses must be present.
- Voting
    - Approval requires a majority of committee members that are present at each meeting.
    - Voting eligibility includes co-chairs, official members, and ad hoc members.
    - Voting may occur in-person or electronically. Electronic voting is permitted only when document approval is time-sensitive for safety or regulatory compliance.
    - Proxy voting is not permitted unless an alternate is officially designated. A proxy will be officially designated by the committee chair(s) following email communication from the appointed committee member. The COS has final approval on the appointment of the proxy voter.

Review & Amendment Process

- This charter will be reviewed every two years or at the request of the COS.
- Amendments to the charter must be approved by voting standards described above and submitted to the MEC for approval.

Table: Committee Membership

Role	Department
Council Co-Chair	Physician of the medical staff
Council Co-Chair	Nursing Leader
Member	VP Quality
Member	CMO or ACMO
Member	CMIO
Member(s)	Chiefs of Staff AHS and AH
Member(s)	Physician representatives from Ambulatory, Anesthesia, Emergency Medicine, Internal Medicine, Obstetrics & Gynecology, Orthopedics, Pediatrics, Psychiatry, Surgery.
Member	Nurse Informatics
Member(s)	RN (1 from each site) - AH, SL, HGH, JGPH, Amb
Member	Nursing Clinical Educator
Member	Pharmacy
Member	Infection Control
Ad Hoc	Specialty nurse
Ad Hoc	Department-based discipline specific rep

ADMINISTRATIVE CLOSURE OF INCOMPLETE RECORDS

Department	Health Information Services	***Effective Date***	04/1993
Campus	All	***Date Revised***	06/2020, 05/2025
Unit	Health Information Services	***Next Scheduled Review***	5/2028
Manual	Health Information Services	***Author***	Director, Health Information Services
Replaces the following Policies:		***Responsible Person***	Chief Information Officer (CIO)

Printed copies are for reference only. Please refer to electronic copy for the latest version.

PURPOSE

To outline the process of and define guidelines for appropriate uses of administrative closure with incomplete records.

POLICY STATEMENT

A medical record shall ordinarily be considered complete when the required documentation has been filed.

No Medical Staff member is permitted to complete a medical record on a patient unfamiliar to him/her in order to close a medical record that was the responsibility of another staff member unless it meets the requirements set forth by the "Documentation by Proxy Power Signature" policy.

When the Health Information Management Department is unable to obtain signatures and necessary record documentation to complete a medical record, they may utilize administrative closure for the incomplete record.

PROCEDURE

1. The Health Information Management Department will make every possible effort to obtain signatures and necessary record documentation on incomplete medical records while the physician is still working at Alameda Health System.

2. The Health Information Management Department will have all the physician's incomplete medical records available for completion.

3. The Health Information Management Department will submit a list of incomplete medical records to the appropriate Medical Staff after a physician has resigned from the Medical Staff.

4. If recommendation is made to administratively close the medical record, the Director of Health Information Management will sign the Administrative Closure of Incomplete Record Form (attachment).

5. When authorizing signature has been obtained, the Health Information Management Department will scan the form in our electronic medical record.

REFERENCES

APPROVALS

		System	Alameda	AHS/Highland/John George/San Leandro
Department:	**Date:**	05/2025		
Pharmacy and Therapeutics (P&T)	**Date:**	N/A	N/A	N/A
Clinical Practice Council (CPC)	**Date:**	7/2025	N/A	N/A
Medical Executive Committee	**Date:**	7/2025		
Board of Trustees	**Date:**	8/2025		

ATTACHMENT

ADMINISTRATIVE CLOSURE OF INCOMPLETE RECORD FORM

Medical Record Number: _____ Encounter Number: _____

Patient Name: _____ Attending: _____

Date of Service: _____ Responsible Physician: _____

Several attempts have been made to complete this medical record. The original author is unable to authenticate. Attempts to obtain proxy signature have been unsuccessful. The Department Chief has been notified.

The Health Information Services Department is requesting that this medical record be administratively closed for the following document:

- ☐ History and Physical
- ☐ Discharge Summary
- ☐ Physician's Order
- ☐ Operative Report
- ☐ Other _____

_____ _____

Director, Medical Records Date

CC: HIM Committee

B3. Recommendation to the Board of Trustees for approval of the AHS Medical Staff Policies and Procedures listed below:

ALAMEDA HEALTH SYSTEM

July 23, 2025

TO: Quality Professional Services Committee

FROM: Berenice Perez, M.D., Alameda Health System Chief of Staff
Catherine Pyun, D.O., Alameda Hospital Chief of Staff

SUBJECT: **Agenda Item:** B3

Meeting Date: July 23, 2025

Item Description: Medical Staff Policies and Procedures

COMMITTEE ACTION: **Recommend Approval of Medical Staff Policies and Procedures**

Background:
The Alameda Health System (AHS) and Alameda Hospital (AH) Medical Staff align policies and procedures to provide continuity across the two Medical Staffs.

The Medical Staff policies provide alignment of credentialing and privileging processes by offering a systematic approach to assessment across our facilities.

Analysis:
The Alameda Health System (AHS) and Alameda Hospital (AH) Medical Staff policies align with the Bylaws and are key to the operational functions and compliance with regulatory requirements.

Board Action Requested: Approval

AHS Medical Staff:

- *Introduction of a New Privilege or New Privilege for a Specific Department or Specialty
- Pain Medicine Anesthesia Standardized Procedure

**Item was agendized in June, resubmitting for approval*

Alameda Health System

INTRODUCTION OF A NEW PRIVILEGE OR A NEW PRIVILEGE FOR A SPECIFIC DEPARTMENT OR SPECIALTY

Department	Medical Staff	***Effective Date***	4/2003
Campus	AHS, AH	***Date Revised***	2/2008, 10/2011, 6/2014, 6/2017, 6/2019, 6/2022, 6/2025
Unit	Medical Staff	***Next Scheduled Review***	6/2028
Manual	Medical Staff	***Author***	Vice President, Physician Services
Replaces the following Policies:		***Responsible Person***	Chief Medical Officer

Printed copies are for reference only. Please refer to electronic copy for the latest version.

Purpose

As medical technology changes, the types of services provided by the Medical Staff also change. As medical technology changes the groups of practitioners within the Medical Staff providing a specific clinical service or procedure may also change. The purpose of this policy is to define the procedure for introducing a new privilege into the Medical Staff or introducing a new privilege into a specific department or specialty.

Policy

All practitioners who provide clinical services at Alameda Health System (AHS) and Alameda Hospital (AH) must be competent to perform the services they provide. When members of different departments or specialties exercise the same privilege, there must be an equivalent comparable standard for the granting of the same clinical privilege in each department or specialty.

Procedure

Introducing a new procedure to AHS and AH

1. If a practitioner or group of practitioners (collectively referred to as "Medical Staff Members") wish to exercise a new privilege at AHS and AH , the Medical Staff Members shall submit the request for the new privilege in writing to the Division Chief (if applicable), Site Director, Department Chair, or Chief of Staff.

2. The Medical Staff Members' request for a new privilege should include the following information:
    a. A detailed description of the privilege.
    b. Copies of scientific articles related to the privilege.
    c. Recommendations for specific training and education necessary to be granted the new privilege.
    d. Recommendations for specific experience and current competence necessary to be granted the new privilege.
    e. Recommendations for proctoring requirements to the new privilege.

   f. Recommendations for the number of times the privilege must be exercised or performed during a two- (2) year reappointment cycle in order to maintain current competence.
   g. Other information that is relevant and required in Attachment A

3. If the new privilege is an update or replacement of an existing privilege and no new additional credentialing criteria are required, this information shall also be submitted to the Division Chief/ Site Director.

4. The Division Chief/Site Director shall review the information submitted and make a recommendation to the Department Chair regarding the addition of the new privilege, and if addition of the privilege is recommended, a recommendation also shall be made regarding criteria for the new privilege. The Division Chief's/Site Director's recommendation shall address items A2 (c-f) described above and include a copy of all relevant supporting documents.

5. The recommendation of the Division Chief/Site Director shall also include submission of Attachment A —"Criteria for New Privilege Delineation."

6. The Department Chair shall review the information submitted and make a recommendation to the Credentials Committee regarding the addition of the new privilege, and if addition of the privilege is recommended, a recommendation also shall be made regarding criteria for the new privilege. The Department Chair's recommendation shall address items A2 (c-f) described above and include a copy of all relevant supporting documents.

7. The recommendation of the Department Chair shall also include submission of Attachment A.

8. The Credentials Committee shall review the recommendation of the Department Chair and shall:
   a. Meet with a representative of the Medical Staff Members requesting the new privilege.
   b. Submit a recommendation to the Medical Executive Committee regarding whether the new privilege should be introduced at AHS and, if so, the specific credentialing criteria to be utilized.

9. The Medical Executive Committee shall review the recommendation of the Credentials Committee and may request an interview with a representative of the Medical Staff Members requesting the new privilege. The recommendation of the Medical Executive Committee regarding the new privilege, including the criteria for granting the new privilege, will be forwarded to the Quality Professional Service Committee (QPSC) of the Board of Trustees for action.

10. Once a new privilege has been approved by favorable recommendation of the Medical Executive Committee, practitioners who meet all applicable criteria may begin to apply for the new privilege. No new privileges will be granted, however,

until the new privilege and associated criteria have been reviewed and approved by the QPSC and appropriate organizational and nursing policies and procedures have been developed and implemented as may be necessary to support the safe and effective performance of the new privilege.

Introducing a new privilege in one department which is currently being granted by another department or specialty

1. The Department Chair, upon recommendation by the Division Chief/Site Director, shall recommend to the Medical Executive Committee the addition of the new privilege to the department privilege delineation form.

2. If the Medical Staff is not currently utilizing appropriate criteria for the privilege, the procedure described in Section A shall be followed to develop appropriate criteria. All departments or specialties that will be granting the privilege will be involved in the criteria development process. The recommendations of this interdepartmental group shall be submitted to the Medical Executive Committee for action.

3. If appropriate criteria for the privilege have already been developed, a meeting will be scheduled to include the Division Chief/Site Director, the Department Chair, and specialty representatives from each department in which the privilege is currently granted and those departments who wish to grant the clinical privilege in the future. The interdepartmental group will meet to assure either development of single criteria that are applicable to all departments and specialties **or** development of multiple equivalent comparable criteria sets.

4. If multiple equivalent comparable criteria sets are designed, the interdepartmental group must assure that a single level of care is maintained relevant to granting of the privilege.

5. The interdepartmental group shall submit a recommendation to the Medical Executive Committee for action.

6. If the interdepartmental group is unable to arrive at consensus related to privilege criteria, the issue will be referred to the Medical Executive Committee for evaluation and action.

7. The Medical Executive Committee may recommend privileging criteria to the QPSC with or without the recommendation of the interdepartmental group.

Medical Executive Committee's Considerations

1. In making a recommendation regarding the granting of a new privilege or extending an existing privilege to a new department or specialty, the Medical Executive Committee shall consider the following:

a. Whether the new privilege may be performed safely using the health system's available resources including facilities, equipment, support personnel, and support services.
b. Whether the current composition of the Medical Staff permits its members to appropriately monitor and review the competence of those who perform the new privilege or whether it is feasible to arrange to have other qualified physicians proctor performance of the new privilege.
c. Whether qualified physicians are available to provide continuous care in the event physicians performing the new privileges are unavailable or ill.
d. Whether sufficient research has been conducted to determine the new privilege is safe and clinically efficacious.
e. Whether the performance of the new privilege poses any bioethical concerns.
f. Whether the benefits of the new privilege outweigh the consequences of not exercising the new privilege.

2. The Medical Executive Committee shall also consider information available from other organizations currently performing the new procedure and/or other organizations that have extended the new privilege to additional departments or specialties.

Quality Monitoring

1. When the Medical Staff has added a new privilege, or a new privilege has been added to a particular department or specialty, the VP/Director of Quality Management (or designee) shall be notified.

2. The VP/Director of Quality Management (or designee shall work with appropriate Medical Staff representatives to determine if and how the new privilege shall be included in the organization's performance improvement program.

3. The Medical Executive Committee, prior to granting the privilege to any Medical Staff Member, shall review issues regarding quality management monitoring related to the privilege.

Approvals

		AHS	Alameda
Medical Executive Committee	**Date:**	**6/18/2025**	**6/20/2025**
QPSC	**Date:**		

ATTACHMENT A

Introduction of a New Privilege or a New Privilege for a Specific Department or Specialty

CRITERIA FOR NEW PRIVILEGE DELINEATION

SPECIFIC PROCEDURE:

DEPARTMENT/DIVISION:

DESCRIPTION:

Training & Education

Experience & Current Competence

Proctoring Requirements

Reappointment Requirements

Recommend ☐ As submitted ☐ With the following modifications

Approval:
Department Chair : _____ Date : _____

Division Chief :_____ Date : _____

Alameda Health System

STANDARDIZED PROCEDURES FOR ADVANCED PRACTICE PROVIDERS IN THE DEPARTMENT OF ANESTHESIA, PAIN MEDICINE DIVISION

Department	Anesthesia, Pain Medicine Division	***Effective Date***	7/2025
Campus	Highland Hospital	***Date Revised***	
Unit	Inpatient/Outpatient	***Next Scheduled Review***	7/2028
Manual	Interdisciplinary Practice	***Author***	Pain Medicine Division Chief
Replaces the following Policies:		***Responsible Person***	Chief of Staff

Procedure Statement

This standardized procedure fulfils Alameda Health System requirements and expectations for defining the scope of practice for Advanced Practice Providers. Standardized procedures are developed collaboratively by nursing, medicine, and administration to comply with the California Business and Profession Code, Nursing Practice Act (NPA) Section 2725 and further clarified in California Code of Regulation (CCR 1480).

Purpose

It is the intent of this document to authorize the Advanced Practice Providers (APP) within the Wilma Chan Highland Hospital Campus in the Department of Anesthesia, Pain Medicine Division to implement the Standardized Procedures without the immediate supervision or approval of a physician. The Standardized Procedures, including all the policies and protocols, are defined in this document, and will be referred to generally as the "Standardized Procedures".

Standardized procedures will be maintained in Policy Tech and reviewed every three (3) years.

Definitions

1. Advanced Practice Provider refers to either Nurse Practitioner or Physician Assistant
    a. **Nurse Practitioner** by definition shall be:
        i. Master's or Doctoral Degree in Nursing
        ii. Current license as a Registered Nurse in California
        iii. Current certification by the State of California, Board of Registered Nursing as a Nurse Practitioner
        iv. California-issued BRN Furnishing Number
        v. Current National Certification
        vi. Active DEA registration number
        vii. National Provider Identification Number
    b. **Physician Assistant** by definition shall be:
        i. Successful completion of a Physician Assistant program of instruction in primary health care approved by the Physician Assisting Examining Committee; OR NCCPA for Physician's Assistant
        ii. Possession of a valid Certificate as a Physician Assistant issued by the California Board of Medical Quality Assurance
        iii. A valid Drug Enforcement Agency (DEA) Number AND Certification by the

National Commission on Certification of Physician Assistants (NCCPA)

iv. National Provider Identifier Number.

All requirements, applications, procedures and duties are the same for both APP classifications, with the exception of issuing drug orders and furnishing, as discussed herein.

2. **Supervising Physician** shall be an attending physician who is a current member in good standing of the Medical Staff, and who holds privileges in the Department of Anesthesia, Pain Medicine Division.

Application

1. In addition to general requirements set forth and described in the Medical Staff Bylaws, Rules and Regulations, policies and privileges forms, the following criteria shall specifically apply to any APPs applying for privileges in the department of Anesthesia, Pain Medicine Division:
   a. A minimum of two (2) years of clinical experience as an APP is preferred. Recent graduates with relevant training may be considered on a case-by-case basis at the discretion of the Division Chief.

Conditions and Standards of Practice

1. **General Conditions**
   a. The APP shall render all care within the standards provided in this document.
   b. The APP shall provide all care in accordance with the laws and regulations of the State of California, and with the Bylaws and Regulations of the Medical Staff and the Department of Anesthesia, Pain Medicine Division.
   c. At no time shall the care rendered by the APP exceed the scope of the licensure. All cases beyond the scope of practice of the APP, and those with which the APP has questions will be referred to the consulting physician.
   d. The APP agrees to work cooperatively with the consulting physician, nursing staff and other health professionals.
   e. The APP shall immediately notify their Division Chief in the event that the practitioner's license to practice is revoked, limited or otherwise affected by action of the Federal or State Health Care Agency, or in the event that they receive any notification or investigation of their license.

2. **Focused Professional Practice Evaluation (FPPE)/Proctoring**

The routine FPPE/Proctoring plan is outlined on the APP privilege form. Once all elements of the FPPE/Proctoring are complete, the outcome of the FPPE will be recorded in the confidential Quality section of the credentials file (maintained by the Medical Staff Office).

During the initial proctoring period, the charts of each patient seen by the APP will be reviewed by the Supervising Physician.

Formal review will be made in writing by the Department Chair or designee initially, and annually, thereafter. The content of such formal evaluation will be discussed with the APP as part of their annual review and kept on file.

3. **Patient Records**

The APP will be responsible for the preparation of a complete medical record for each patient contact per existing Alameda Health System policies and Medical Staff Bylaws, Rules & Regulations and policies.

4. **Supervision**

The APP is authorized to implement the Standardized Procedures in this document without the direct or immediate observation, supervision or approval of a physician, except as may be specified in the Scope of Practice. In accordance with Medical Staff Bylaws, Rules & Regulations and policies, the supervising

physician is ultimately responsible for adherence to this protocol and for the quality of care provided by APP in their respective areas. Physician consultation is available at all times, either on-site, telephone, or by electronic means.

Scope of Practice

1. **Policy**

APPs are authorized to diagnose and treat medical problems according to accepted criteria and management including, but not limited to:

a. Assessment and management of acute, perioperative, chronic and cancer-related pain
b. Performance of pain-focused physical exams
c. Ordering and interpreting imaging and laboratory studies relevant to pain conditions
d. Formulation and implementation of multimodal pain treatment plans, including pharmacologic and non-pharmacologic therapies
e. Patient and family education regarding pain conditions and treatment options
f. Collaboration with interdisciplinary team members including primary care, oncology, palliative care, physical therapy, and behavioral health
g. Coordination of interventional pain procedures, including patient preparation and post-procedural follow-up
h. Prescription and monitoring of controlled substances in compliance with institutional and regulatory guidelines
i. Participation in quality improvement initiatives, clinical documentation, and activities as required by the department or institution

2. **Authorized Duties and Practice**

The APP is authorized to do the following patient-related activities within the scope of practice defined by Title 16:

a. Take the patient's medical history and perform a physical examination for any presenting problem;
b. Order specific laboratory studies and x-rays, and other studies as appropriate for that patient;
c. Collect specimens as indicated for additional tests;
d. Perform pertinent laboratory tests in compliance with Clinical Laboratory regulations;
e. Perform any other procedure for which they have been granted privileges;
f. Counsel patients and their families on health promotion, diagnosis and management options;
g. Diagnose and treat acute, perioperative, chronic and cancer-related pain;
h. Complete medical records for every patient encounter in the department of Anesthesia, Pain Medicine Division computer-based format followed by all providers in the Department of Anesthesia, Pain Medicine Division.

3. **Procedures and Minor Surgeries**

a. APP at time of hire will need to demonstrate competency in each of the basic Pain Medicine skills. Advanced procedures require proctoring and advanced attending approval before procedure is initiated in the Pain Medicine patient. The APP will follow existing Pain Medicine department protocols for each procedure done in the Pain Medicine patient, including sterile procedure, sedation, observation and confirmatory testing.
b. For procedures that require consent APP will be responsible for obtaining informed consent from the patient
c. At the completion of the procedure the APP will write a procedure note that includes and complications and the name of the attending physician.
d. The APP can perform the following list of procedures for Pain Medicine patients once granted privileges and demonstrated competency by direct observation or documented prior work experience.

i. Pain Medicine procedures (in accordance with the privilege form)
   - Trigger point injections
   - Subcutaneous or intramuscular medication administration
   - Peripheral joint or bursal corticosteroid injections (e.g., trochanteric bursa, knee, shoulder)
   - Catheter (e.g., epidural and/or peripheral nerve) removal
   - Wound and dressing change
   - Spinal cord stimulator (SCS) trial lead removal

4. **Protocols**
   a. The APP has been granted privileges within the Alameda Health System to perform the requested procedures.
   b. The APP has been trained to perform the procedure(s), has been observed satisfactorily performing the procedure(s) by another provider competent in that skill, and continued competency is assessed per AHS policy.
   c. The APP is following standard medical technique for the procedures as described in the Resources listed in this document.
   d. Appropriate patient consent is obtained, if necessary, before the procedure.
   e. Unless otherwise exempt, all biopsied tissue is sent for a pathology report.
   f. All other applicable Standardized Procedures in this document are followed during health care management.
   g. All General Policies regarding Review, Approval, Setting, Education, Evaluation, Patient Records, Supervision and Consultation in these Standardized Procedures are in force.

Drug Orders and Furnishing

POLICY
The APP is authorized to furnish or order drugs and devices under the following protocols:

PROTOCOLS
1. The APP has a current Furnishing, NPI, and DEA number.
2. The drugs and devices ordered or furnished are consistent with the APP's educational preparation or for which clinical competency has been established and maintained and listed in the AHS formulary, the patient's insurance formulary, non-formulary medications for which there are no substitutes, or practice recommendations listed in the Resources in this document. Examples are listed in the "Formulary" document at the end of this Standardized Procedure.
3. The drug or device furnished or ordered is appropriate to the condition being treated.
4. APPs may order or prescribe those medications that are FDA approved unless it is used in a clinical investigation, such as a clinical trial, which must be approved by AHS IRB. Additionally, expanded access, sometimes called "compassionate use," may be used when it is outside of a clinical trial of an investigational medical product. Prior IRB review and approval is required, even if only one patient is to be treated under this procedure. Prior approval by the FDA is also required for these cases.
5. "Off label" use, or prescription of FDA-approved medications for uses other than that indicated by the FDA, is permitted when such practices are within the current standard of care for treatment of the disease or condition.
6. Patient education is given regarding the drug or device.
7. The Statement of Approval and Agreement signed by the APP will act as the record of APP authorized to Furnish.

8. No single physician will supervise more than four APPs at any one time.
9. A physician must be available at all times in person or by telephonic contact.
10. All other applicable Standardized Procedures in this document are followed during health care management.
11. All General Policies regarding Review, Approval, Setting, Education, Evaluation, Patient Records, Supervision and Consultation in these Standardized Procedures are in force.

Ordering scheduled Controlled Substances

POLICY
The APP is authorized to furnish or order scheduled controlled substances per the following protocols:

PROTOCOLS
1. The APP follows the provisions of the Standardized Procedure for Furnishing.
2. The controlled substances that may be ordered are included in the formulary(s) or references listed in this document.
3. Relevant scheduled drug contracts, DEA requirements, and all State and Federal regulations are adhered to.
4. Schedule II & III controlled substances are furnished or ordered following the Patient Specific Protocol, in addition to these General Protocols for Scheduled Controlled Substances.
5. The APP may furnish, prescribe or order any medications on the patient's insurance formulary or non-formulary medications for which there is no substitute, within the scope of the provider's license and within the scope of AHS ordering policies.
6. All other applicable Standardized Procedures in this document are followed during health care management.
7. All General Policies regarding Review, Approval, Setting, Education, Evaluation, Patient Records, Supervision and Consultation in these Standardized Procedures are in force.

SCHEDULE III PATIENT SPECIFIC PROTOCOL
1. Schedule III substances may be furnished or ordered when the patient is in one of the following categories, including but not limited to the following conditions:
    a. Acute illness, injury or infection: such as cough, fractures
    b. Acute intermittent but recurrent pain: such as headache
    c. Chronic continuous pain
    d. Hormone replacement

2. Limit order for acute illness, injury or infection to a maximum of 30 days & no refills without re-evaluation.

3. For chronic conditions:
    a. Pain management protocol or department guidelines is/are adhered to, if appropriate.
    b. Amount given, including all refills (maximum of 5 in 6 months per DEA regulations, is not to exceed a 120 day supply as appropriate for the condition.
    c. Treatment plan must be established in collaboration with the patient's primary care provider and reviewed, with documentation, every 6-12 months.
    d. No further refills without reevaluation.

4. Education and follow-up is provided.

SCHEDULE II PATIENT SPECIFIC PROTOCOL

1. Schedule II controlled substances may be ordered when the patient has one of the following diagnoses and under the following conditions.
   a. Pain from cancer, post-operative pain, and trauma.
   b. Pain unresponsive to, or inappropriately treated by CS III-V substances
   c. Attention Deficit Hyperactivity Disorder (ADHD)
   d. Neuropsychiatric Conditions
2. Limit order for acute and chronic conditions as specified above in Schedule III Protocol.
3. No refills for CS II medications are authorized except where authorized by the DEA.
4. Pain Management Protocol or Department guidelines is/are adhered to if appropriate.

Medication Management

POLICY

The APP is authorized to manage drugs and devices under the following protocols:

PROTOCOLS

1. The management of drugs or devices includes evaluating, initiating, altering, discontinuing, furnishing and ordering of prescriptive and over-the-counter medications.
2. Medication evaluation includes assessment of:
   - Other medications being taken.
   - Prior medications used for current condition.
   - Medication allergies and contraindications, including appropriate labs and exams.
3. The drug or device is appropriate to the condition being treated, and:
   - Accepted dosages per references.
   - Generic medications are ordered if appropriate.
4. A plan for follow-up and refills is written in the patient's chart.
5. The prescription must be written in patient's chart including name of drug, strength, instructions and quantity, and signature of the APP.
6. All other applicable Standardized Procedures in this document are followed during health care management.
7. All General Policies regarding Review, Approval, Setting, Education, Evaluation, Patient Records, Supervision and Consultation in these Standardized Procedures are in force

Authorizations

POLICY

The APP is authorized, under the following protocols, to:

- Assess Worker's Compensation injuries and illnesses
- Certify Disability
- Manage Home Health and Personal Care Services
- Order Restraint and Seclusion

PROTOCOLS

1. Workers' Compensation: The Doctor's First Report of Occupational Injury or Illness for a workers' compensation claim can be for a period of time off in relation to injury. The treating physician is required to sign the report and to make any determination of any temporary disability.
2. Certify Disability: The APP has performed a physical exam and collaborated with a physician and surgeon.

3. Home Health and Personal Care Services: Approval, signing, modifying, or adding to a plan of treatment or plan of care
4. Restraint and Seclusion: The APP must be knowledgeable and competent in the Hospital Conditions of Participation for Patients' Rights including the Interpretive Guidelines. Ordering physical or chemical restraint, and/or seclusion, is in strict accordance with the protocols adopted in the Resources section of this document which include the extent of implementation and which meets the intent of the acute medical and surgical hospitals Conditions of Participation for Rights.
5. All other applicable Standardized Procedures in this document are followed during health care management.
6. All general policies regarding review, approval, setting, education, evaluation, patient records, supervision and consultation in these standardized procedures are in force.

5. **Standard of Care**

Standards for adequacy of diagnosis, management and treatment shall be in accordance with hospital Policy and Procedure, clinic protocols, current community standards of care, Anesthesia, Pain Medicine Division Department protocols or current texts/articles on care found in the Department of Anesthesia, Pain Medicine Division.

6. **Consultation and Referral**

The APP will be providing health care as outlined in this document. In general, communication with a physician who is a current member in good standing of the Medical Staff, and who holds privileges in the Department of Anesthesia, Pain Medicine Division will be sought for all the following situations, and any others deemed appropriate. Whenever a physician is consulted, a notation to that effect, including the physician's name, must be made in the chart.

a. Conditions that do not follow clinical protocols, procedures, classic diagnostic patterns, or that have failed to respond to standardized treatments and/or management.
b. Any significant unexplained physical or historical findings.
c. Emergency situations after initial care.
d. When the patient expresses a desire to see a physician.

The following situations are examples (not exhaustive) of those that will likely require physician advice or consultation:

e. Persistent or worsening pain despite standard multimodal therapy, including opioid rotation or escalation.
f. Requests for initiation or continuation of high-dose opioids outside institutional opioid stewardship thresholds.
g. New or worsening neurologic deficits (e.g., foot drop, saddle anesthesia, bowel/bladder changes).
h. Suspected spinal cord compression or cauda equina syndrome.
i. Complications related to interventional procedures (e.g., infection, hematoma, unintentional dural puncture).
j. Requests for interventional procedures requiring physician oversight (e.g., epidural steroid injection, sympathetic blocks, spinal cord stimulator trials).
k. Patient with poorly controlled psychiatric comorbidities impacting pain management (e.g., suicidality, substance use disorder, somatization).
l. Complex diagnostic uncertainty requiring specialist input (e.g., unexplained pelvic pain with negative imaging and labs).
m. Requests for medical cannabis, ketamine, or off-label controlled substances.

7. **Other duties**

The patient must be informed that the provider is an APP and be given the opportunity to request care by a

physician should the patient desire it.

8. **APP - Nursing Staff Relationship**

The APP is authorized to give nursing personnel orders for all laboratory and x-ray studies, treatment and medication for those patients for whom the APP is providing medical care. Orders given by the APP are orders generated in agreement with the Consulting Physician. Any questions regarding these orders that are not satisfactorily resolved through discussion with the APP should be brought to the Consulting Physician before being carried out.

9. **Agreement Review**

The signature on the Attestation by the APP acknowledges agreement to practice within the limits of the foregoing standardized procedures/practice guidelines. Upon its review, if changes are made, new signatures will be necessary.

10. **References/Resources**

- AHS/AH Medical Staff Bylaws
- Medical Staff Advanced Practice Provider policy and procedure manual
- Medical Staff Privilege forms
- Nurse Practice Act in the California Business and Professions Code
- Physician Assistant Practice Act
- References that define Standard of care for the include, but are not limited to:
  - o UpToDate
  - o Roberts and Hedges Procedural Book
  - o AHS Formulary for drug use and current antibiogram

Approvals:

Committee on Interdisciplinary Practice	6/4/25
Credentials Committee	6/12/25
CPC	7/3/25
Medical Executive Committee	7/16/25
QPSC	7/23/25

Signature:

Signature implies the following: approval of all the policies and protocols in this document, the intent to abide by the Standardized Procedures, the willingness to maintain a collegial and collaborative relationship with all the parties, and agreement of all collaborating/supervising physicians within the department.

Nurse Practitioner/Physician Assistant (Printed Name): _____

Signature:_____ Date: _____

B4. Approval of the AHS Medical Staff Revised Application Forms and Revised Privilege Forms listed below:

ALAMEDA HEALTH SYSTEM

July 23, 2025

TO: Quality Professional Services Committee

FROM: Berenice Perez, M.D., Alameda Health System Chief of Staff
Catherine Pyun, D.O., Alameda Hospital Chief of Staff

SUBJECT: **Agenda Item:** B4

Meeting Date: July 23, 2025

Item Description: Medical Staff Application & Specialty Privilege Forms

COMMITTEE ACTION: Approval of revised Medical Staff Privilege Forms

Background:
The specialty privilege form(s) listed in the analysis section are revised privileges forms, designed to offer a systematic approach for care across our facilities (AHS, SLH, AH) as applicable.

Analysis:
The Medical Staff application includes questionnaires intended to collect documentation used in the decision-making process for credentialing applicants that are applying to the Medical Staff.

Whether new or revised, the Medical Staff privilege forms are updated through a succinct process using best practice and clinical evidence.

Board Action Requested:
Approval of application form revisions and revised privilege forms, that offer a system-wide approach for credentialing and privileging providers that support patient care at AHS.

Revised Application Forms for AHS & AH:
- Confidentiality Agreement Form for Remote Meeting Access (revision) – for non-Medical Staff
- Confidentiality Agreement for Medical Staff Affairs (revision) – for Medical Staff/APP inclusion in application/reapplication
- Malpractice Claims History

Revised Privilege Forms for AHS:
- Pain Medicine – Advanced Practice Provider
- Physical Medicine and Rehabilitation Advanced Practice Provider

Alameda Health System Medical Staff and Alameda Hospital Medical Staff

CONFIDENTIALITY AGREEMENT FORM FOR REMOTE MEETING ACCESS

(Non-Medical Staff)

It is the policy of the Alameda Health System Medical Staff and Alameda Hospital Medical Staff to maintain the confidentiality of all medical staff records and proceedings. Those privy to such information shall not disclose, either intentionally or unintentionally, confidential information belonging to, or obtained through their participation in Medical Staff affairs to any person, organization or entity, including other medical staff organizations, their relatives, friends, business and professional associates, unless the Hospital Medical Staff has authorized disclosure. This policy is not intended to prevent disclosure where disclosure is required by law.

As a member or guest of a Medical Staff Committee involved in the evaluation and improvement of the quality of care rendered at Alameda Health System, I recognize that confidentiality is vital to the free and candid discussions necessary to effective Medical Staff activities. Therefore, I agree to respect and maintain the confidentiality of all discussions, deliberations, records, and other information generated in connection with these activities and to make no voluntary disclosures of such information except to persons authorized to receive it in the conduct of Medical Staff affairs.

Furthermore, my participation in peer review and quality assessment activities is in reliance on my belief that confidentiality will be respected and maintained by every other member of the Medical Staff, Advanced Practice Provider Staff or other individuals involved. I understand the Hospital, the Medical Staff and Advanced Practice Providers are entitled to undertake such action as is deemed appropriate to ensure that this confidentiality is maintained, including action necessitated by any breach or threatened breach of this agreement in accordance with Medical Staff Bylaws and applicable Policy and Procedures, and I agree to abide by applicable laws, regulations & standards (whether federal, state or local).

As authorized by the Medical Executive Committee, confidential Medical Staff committee meetings may be conducted through electronic, video or digital technology, (e.g., Teams, Zoom, Webex, etc.). All information discussed during such meetings is confidential peer review information that is protected under California Evidence Code Section 1157. To ensure that confidentiality is upheld, members and guests are required to attend meetings in an environment that allows for privacy. This means an area that is not in view, hearing or recording of any individual who is not authorized to attend the meeting. I further agree that I will not save, forward, take a screen shot or otherwise retain or share agendas, minutes or other materials reviewed at the meeting.

By signing this form, I agree to observe the confidentiality requirements of the Hospital, Medical Staff and recognize a breach of such confidentiality may subject me to disciplinary action pursuant to the Medical Staff Bylaws.

Signature _____ Date _____

Printed Name: _____

To be included in the provider initial and reappointment applications as a form, replacing the existing statements.

Alameda Health System Medical Staff and Alameda Hospital Medical Staff

MEDICAL STAFF/ADVANCED PRACTICE PROVIDER CONFIDENTIALITY AGREEMENT FORM FOR MEDICAL STAFF AFFAIRS

It is the policy of the Alameda Health System Medical Staff and Alameda Hospital Medical Staff that members of the Medical and Advanced Practice Providers Staff will not disclose either intentionally or unintentionally, confidential information belonging to, or obtained through their affiliation with the Hospital Medical Staff to any person, organization or entity, including other medical staff organizations, their relatives, friends, business and professional associates, unless the Hospital Medical Staff has authorized disclosure. This policy is not intended to prevent disclosure where disclosure is required by law.

As a member, or potential member, of a Medical Staff Committee involved in the evaluation and improvement of the quality of care rendered at Alameda Health System, I recognize that confidentiality is vital to the free and candid discussions necessary to effective Medical Staff activities. Therefore, I agree to respect and maintain the confidentiality of all discussions, deliberations, records, and other information generated in connection with these activities and to make no voluntary disclosures of such information except to persons authorized to receive it in the conduct of Medical Staff affairs.

Furthermore, my participation in peer review and quality assessment activities is in reliance on my belief that confidentiality will be respected and maintained by every other member of the Medical Staff, Advanced Practice Provider Staff or other individuals involved. I understand the Hospital, the Medical Staff and Advanced Practice Providers are entitled to undertake such action as is deemed appropriate to ensure that this confidentiality is maintained, including action necessitated by any breach or threatened breach of this agreement in accordance with Medical Staff Bylaws and applicable Policy and Procedures, and I agree to abide by applicable laws, regulations & standards (whether federal, state or local).

As authorized by the Medical Executive Committee, confidential Medical Staff committee meetings may be conducted through electronic, video or digital technology, (e.g., Teams, Zoom, Webex, etc.). All information discussed during such meetings is confidential peer review information that is protected under California Evidence Code Section 1157. To ensure that confidentiality is upheld, Medical Staff members are required to attend meetings in an environment that allows for privacy. This means an area that is not in view, hearing or recording of any individual who is not authorized to attend the meeting. I further agree that I will not save, forward, take a screen shot or otherwise retain or share agendas, minutes or other materials reviewed at the meeting.

By signing this form, I agree to observe the confidentiality requirements of the Hospital Medical Staff and recognize a breach of such confidentiality may subject me to disciplinary action pursuant to the Medical Staff Bylaws. This agreement remains in effect until rescinded by me in writing to the Chief of Staff.

To be included in the provider initial and reappointment applications as a form, replacing the existing statements.

_____ _____

Signature Date

_____

Printed Name

To be included in the provider initial and reappointment applications as a form, replacing the existing statements.

*Existing MS/APP application statement to be removed and replaced with the proposed form:

Virtual Meeting Confidentiality Agreement	
Yes	By checking this box, I agree to observe the confidentiality requirements of the Hospital Medical Staff and recognize a breach of such confidentiality may subject me to disciplinary action pursuant to the Medical Staff

	Bylaws.
It is the policy of the Alameda Health System Medical Staff and Alameda Hospital Medical Staff that members of the Medical and Allied Health Professional Staff will not disclose either intentionally or unintentionally, confidential information belonging to, or obtained through their affiliation with the Hospital Medical Staff to any person, organization or entity, including other medical staff organizations, their relatives, friends, business and professional associates, unless the Hospital Medical Staff has authorized disclosure. This policy is not intended to prevent disclosure where disclosure is required by law.	
As authorized by the Medical Executive Committee confidential Medical Staff committee meetings may be conducted through electronic, video or digital technology, (e.g., Teams, Zoom, Webex, etc.). All information discussed during such meetings is confidential peer review information that is protected under California Evidence Code Section 1157. To ensure that confidentiality is upheld, Medical Staff members are required to attend meetings in an environment that allows for privacy. This means an area that is not in view, hearing or recording of any individual who is not authorized to attend the meeting. I further agree that I will not save, forward, take a screen shot or otherwise retain or share agendas, minutes or other materials reviewed at the meeting.	

Alameda Health System Medical Staff Services

Professional Liability Action Explanation (Malpractice Claims History)

In the past 10 years (for initial applicants) or since your last appointment (for reapplicants), have you had any professional liability actions/malpractice claims made against you?

Professional liability actions include any pending (including notice of intent to sue), settled, arbitrated, mediated, litigated, alternative dispute resolution process, dismissed or judgment, including those made against you and/or settled prior to a lawsuit being filed or prior to the commencement of an arbitration. (Please use a separate form for each action).

No Yes (provide information below for each case):

Date of Alleged Incident *(month/day/year):* Date Claim Filed *(month/day/year):*

Claim Status: Open Closed

Insurance Carrier Name:

Claim Settlement Date (if closed) *(month/day/year):* Settlement Amount (if closed): $

Resolution Method (if closed):

Arbitration	Judgment for Plaintiff	Dismissed
Mediation	Judgment for Defendant	Settled

Alternative dispute process (explain): _____

Summarize the circumstances given rise to the action, including your description of your care and treatment of the patient. Include 1) condition and diagnosis at the time of incident, 2) dates and description of treatment rendered, and 3) condition of patient subsequent to treatment.

Description of Allegation(s):

Your involvement in the case (attending, surgeon, consultant, etc.):

Were you the primary defendant? Yes No Number of Co-defendants:

Description of alleged injury to patient:

Did the alleged injury result in death? Yes No

To the best of your knowledge, is this case included in the National Practitioner Data Bank (NPDB)?

Yes No

With my signature below, I attest that the above information is accurate. I further agree to notify Alameda Health System in a timely manner of any change to the information included in this form.

Signature: Printed Name:

Date:

Pain Medicine – Advanced Practice Provider - AHS

Delineation of Privileges

Applicant's Name:

Instructions:

1. Click the **Request** checkbox to request a group of privileges such as *Core Privileges* or a *Special Privileges*.
2. Uncheck any privileges you do not want to request in that group.
3. Check off any special privileges you want to request.
4. Sign form and submit with any required documentation.

Required Qualifications	
Education/Training	Physician Assistant: Successful completion of an accredited Physician Assistant Education program which meets the requirements required for licensure and Physician Assistant certification. Nurse Practitioner: Successful completion of a graduate program for the education and preparation of nurse practitioners or meet the training/education requirements according to Title 16, Article 8, Section 1482; BPC Section 2834-2837.
Licensure	Physician Assistant: Licensed as a Physician Assistant by the Physician Assistant Board of California. Nurse Practitioner: Licensed as a registered nurse by the California Board of Registered Nursing AND license certification as a Nurse Practitioner by the California Board of Registered Nursing.
Certification	Physician Assistant: Certification by the National Commission on Certification of Physician Assistants (NCCPA). Nurse Practitioner: Certification by the American Nurses Credentialing Center (ANCC), American Academy of Nurse Practitioners Certification Board (AANP), or American Association of Critical-Care Nurses (AACN).
Clinical Experience (Initial/Reappointment)	Physician Assistant/Nurse Practitioner: Recent training and/or clinical experience is required for all applicants for appointment and reappointment. Recent clinical experience is defined as having performed at least 100 patient encounters or procedures relevant to privileges requested within the preceding two (2) years.
Additional Qualifications	Physician Assistant: Signed Standardized Procedure AND Practice Agreement/Delegation of Services Agreement. Nurse Practitioner: Signed Standardized Procedure AND California Nurse Practitioner Furnishing Number. **AND** Supervising Physician Agreement Current DEA registration

Core Cognitive Practice Prerogatives

Description: Privileges available to the Advanced Practice Provider (PA or NP).

Request ☐	***Request all privileges listed below.*** *Uncheck any privileges that you do not want to request.*	Div Chief Rec ☐	Dept Chair Rec ☐
☐	Outpatient consultation and management	☐	☐
☐	Inpatient consultation and management	☐	☐
☐	Obtain a patient medical history and perform a physical exam	☐	☐
☐	Order, conduct, interpret labs, imaging studies and other diagnostic tests	☐	☐
☐	Provide patient and family education regarding diagnosis, treatment options, prognosis, and strategies for health maintenance and disease prevention	☐	☐
☐	Administer, provide or transmit medication orders according to protocols	☐	☐

Focused Professional Performance Evaluation (FPPE)/Initial Proctoring Requirements

☐ First six (6) clinical activities including first three (3) office visit notes and first three (3) inpatient consult notes.

Medication Management

Request ☐	***Request all privileges listed below.*** *Uncheck any privileges that you do not want to request.*	Div Chief Rec ☐	Dept Chair Rec ☐
☐	Controlled Medication Outpatient Prescription: Prescribe and manage DEA full schedule medications (2, 2N, 3, 3N, 4, 5) in outpatient setting including narcotics and provide treatment within APP scope of practice and consistent with APP skills, training, and professional judgment. Prescribing shall be performed in accordance with DEA licensure, state law, and Standardized Procedures.	☐	☐
☐	Management of outpatient non-opioid medications relevant to chronic pain including prescribing, safe monitoring, and dose titration	☐	☐

Focused Professional Performance Evaluation (FPPE)/Initial Proctoring Requirements

☐ Three (3) chart reviews of controlled outpatient medication management

Procedural Practice Prerogatives

Request ☐	***Request all privileges listed below.*** *Uncheck any privileges that you do not want to request.*	Div Chief Rec ☐	Dept Chair Rec ☐
☐	Trigger point injections	☐	☐
☐	Subcutaneous or intramuscular medication administration/injections	☐	☐

☐	Peripheral joint or bursal corticosteroid injections (e.g., trochanteric bursa, knee, shoulder)	☐	☐
☐	Catheter removal (e.g., epidural and/or peripheral nerve)	☐	☐
☐	Wound or Dressing Management	☐	☐
☐	Spinal cord stimulator (SCS) trial lead removal	☐	☐

Focused Professional Practice Evaluation (FPPE)/ Initial Proctoring Requirements

☐ Review of two (2) procedures representative of the scope and complexity of privileges requested.

☐

Telemedicine Privileges Inpatient or Outpatient Care

Description: These privileges are intended to support existing specialty privileges for physicians and Advanced Practice Providers who are not otherwise classified as Telemedicine ONLY providers.

Qualifications

Qualifications Clinical services are limited to only those aspects of existing privileges granted that can be provided remotely.

Request		***Request all privileges listed below.***
AHS Core	**AH**	Click **shaded blue check box** to Request all privileges. Uncheck any privileges you do not want to request.
☐	☐	☐ **- Currently granted privileges**
☐	☐	Telehealth initial and follow up consultations
☐	☐	Virtual Check-ins
☐	☐	E-Visits

Acknowledgment of Applicant

I have requested only those privileges for which by education, training, current experience, and demonstrated competency I believe that I am competent to perform and that I wish to exercise at Alameda Health System and I understand that:

A. In exercising any clinical privileges granted, I am constrained by applicable Hospital and Medical Staff policies and rules applicable generally and any applicable to the particular situation.

B. Any restriction on the clinical privileges granted to me is waived in an emergency situation and in such situation my actions are governed by the applicable section of the Medical Staff Bylaws or related documents.

Practitioner's Signature _____ Date _____

Department Chair Recommendation - Privileges

I have reviewed the requested clinical privileges and supporting documentation and make the following recommendation(s):

Privilege	Condition/Modification/Deletion/Explanation

Division Chief Recommendation - FPPE Requirements

Signature of Division Chief/Designee

Date

Signature of Department Chair/Designee

Date

Submit

Physical Medicine & Rehabilitation - APP

Delineation of Privileges

Applicant's Name:

Instructions:

1. Click the **Request** checkbox to request a group of privileges such as *Core Privileges* or a *Special Privileges*.
2. Uncheck any privileges you do not want to request in that group.
3. Check off any special privileges you want to request.
4. Sign form and submit with any required documentation.

Required Qualifications	
Education/Training	Physician Assistant: Successful completion of an accredited Physician Assistant Education program which meets the requirements required for licensure and Physician Assistant certification. - Nurse Practitioner: Successful completion of a graduate program for the education and preparation of nurse practitioners or meet the training/education requirements according to Title 16, Article 8, Section 1482; BPC Section 2834-2837.
Licensure	Physician Assistant: Licensed as a Physician Assistant by the Physician Assistant Board of California. - Nurse Practitioner: Licensed as a registered nurse by the California Board of Registered Nursing AND license certification as a Nurse Practitioner by the California Board of Registered Nursing.
Certification	Physician Assistant: Certification by the National Commission on Certification of Physician Assistants (NCCPA). - Nurse Practitioner: Certification by the American Nurses Credentialing Center (ANCC), American Academy of Nurse Practitioners Certification Board (AANP), or American Association of Critical-Care Nurses (AACN).
Clinical Experience (Initial/Reappointment)	Physician Assistant/Nurse Practitioner: Recent training and/or clinical experience are required for all applicants for appointment and reappointment. Recent clinical experience is defined as having performed at least 200 care activities relevant to practice prerogatives requested in the preceding two (2) years.
Additional Qualifications	Physician Assistant: Practice Agreement/Delegation of Services Agreement. - Nurse Practitioner: Signed Standardized Procedure AND California Nurse Practitioner Furnishing Number. **AND** Supervising Physician Agreement Current DEA registration

Practice Prerogatives: Physical Medicine and Rehabilitation

Description: Privileges available to the PA or NP working in the Division of Physical Medicine and Rehabilitation.

Request	***Request all privileges listed below.*** *Uncheck any privileges that you do not want to request.*	Div Chief Rec	Dept Chair Rec
	Obtain patient's medical history and perform a physical examination		
	Conduct the initial and ongoing assessment of the patient's medical and physical status		
	Order, conduct, interpret labs, x-rays, and other diagnostic studies		
	Counsel patients and their families on health promotion, diagnosis, and management options		
	Facilitate and initiate referrals to appropriate health care agencies and arranging for community resources		
	Diagnose and treat rehabilitation and medical conditions		
	Prepare patient discharge medications and orders		
	Administer, provide, or transmit drug orders or devices according to protocols and the requirements in the Advanced Practice Provider policy manual		

Focused Professional Practice Evaluation (FPPE)/Routine Proctoring Requirements

First five (5) clinical activities include first three (3) H&Ps.

Procedural Practice Prerogatives

Request	***Request all privileges listed below.*** *Uncheck any privileges that you do not want to request.*	Div Chief Rec	Dept Chair Rec
	Removal of sutures/staples		
	Removal PEG tubes		
	Wound vacuum changes		
	Wound dressing changes		

Focused Professional Practice Evaluation (FPPE)/Routine Proctoring Requirements

Three (3) chart reviews representative of the scope and complexity of privileges requested.

Telemedicine Privileges Inpatient or Outpatient Care

Description: These privileges are intended to support existing specialty privileges for physicians and Advanced Practice Providers who are not otherwise classified as Telemedicine ONLY providers.

Qualifications

Qualifications Clinical services are limited to only those aspects of existing privileges granted that can be provided remotely.

Request	***Request all privileges listed below.*** *Uncheck any privileges that you do not want to request.*	Div Chief Rec	Dept Chair Rec
	Telehealth initial and follow up consultations		
	Virtual Check-ins		
	E-Visits		

Acknowledgment of Applicant

I have requested only those privileges for which by education, training, current experience, and demonstrated competency I believe that I am competent to perform and that I wish to exercise at Alameda Health System and I understand that:

A. In exercising any clinical privileges granted, I am constrained by applicable Hospital and Medical Staff policies and rules applicable generally and any applicable to the particular situation.

B. Any restriction on the clinical privileges granted to me is waived in an emergency situation and in such situation my actions are governed by the applicable section of the Medical Staff Bylaws or related documents.

Practitioner's Signature

Date

Department Chair Recommendation - Privileges

I have reviewed the requested clinical privileges and supporting documentation and make the following recommendation(s):

Privilege	Condition/Modification/Deletion/Explanation

Division Chief Recommendation - FPPE Requirements

Signature of Division Chief/Designee

Date

Signature of Department Chair/Designee

Date

C. Medical Staff Reports

Alameda Hospital Medical Executive Committee (MEC)
and
Alameda Health System Medical Executive Committee (MEC)
Report to the Quality Professional Services Committee of the Board

SUBJECT:	**Agenda Item:** C
Meeting Date:	July 23, 2025
Item Description:	Medical Staff Executive Committee Combined Report
FROM:	Berenice Perez, M.D., Alameda Health System Chief of Staff Catherine Pyun, D.O., Alameda Hospital Chief of Staff

The report below is being submitted to the Quality Professional Services Committee of the Board of Trustees by the Alameda Health System (AHS) and Alameda Hospital (AH) Medical Executive Committee(s).

AHS Clinical Practice Committee

The Medical Executive Committee (MEC) reviewed and approved multiple policies and physician order sets, which have been included in the QPSC consent agenda for Board approval.

Administrative Reports

The Executive Leadership Team presented to the MEC:

- Proposed Federal Medicaid Cuts
- Immigration Taskforce
- Chief Medical Officer (CMO) Search
- Psychiatry Department Chair job description revised which will result in the launch of the Search Committee
- Medical Director Roles: There are three new roles. John George and Addiction Medicine who will report to the Department Chairs and work with their dyad partners. The Utilization Management Medical Director will report to the CMO.
- Evidence-based and data-driven initiatives will be priorities going forward through a transformation team.
- AI Taskforce responsible, equitable use of technology to develop a roadmap, develop leadership with an organizational level approach and alignment across teams

The Medical Executive Committee expressed appreciation to Dr. Beth Mahler, Interim CMO who is transitioning out of AHS. Dr. Mahler shared her experience with the physician leadership for their efforts and commitment through engagement in patient care, focus on patient/provider experience and quality care.

Alameda Hospital Medical Executive Committee (MEC)
and
Alameda Health System Medical Executive Committee (MEC)
Report to the Quality Professional Services Committee of the Board

AHS Medical Staff Quality & Safety Committee

The committee reported on the Quality Objectives and Key Results (ORK)/ Key Performance Indicators (KPI) Dashboards with May 2025 data.

Quality Objectives and Key Results Dashboards (April 2025) - 33 harmful events (falls, HAPI, behavioral events with physical injury) were reported. ED Boarding Time for Admitted Patients performance slightly increased, HGH 11.44 hours were reported for May 2025, above goal of 8:32. For SLH, 2.53 hours, above goal of 2.20 hours, and AH 2.37 hours, above goal of 2.20.

AHS Medical Staff Patient Safety Committee

The committee reported on the causes, contributing factors, and process improvement plans of one Root Cause Analysis.

AHS Operating Room Committee

The report was presented using the SWOT format.

Strengths

- Mission-driven, highly committed team
- Engaged, active multi-disciplinary team

Weaknesses

- Aging infrastructure and equipment
- Limited established process/systems/policies
- Limited data and analytics
- Communication challenges

Opportunities

- Process improvement initiatives
- Safety and quality metrics/programs
- Interdisciplinary collaboration
- Improved executive sponsorship

Threats

- Inability to address systemic issues beyond the OR
- Administrative pressure to address financial constraints
- Workforce disengagement and resistance to standardizing work

Support Needed

Patient Care:

- Safety and Quality metrics/key indicator development: i.e., patient experience, SSI reduction, death rates, adverse drug events
- Referral and access measures for surgical care: time to OR for elective and non-elective surgery

Report to QPSC is from the Alameda Health System Medical Staff (on July 16, 2025) and Alameda Hospital Medical Executive Committees (on July 18, 2025).

Alameda Hospital Medical Executive Committee (MEC)
and
Alameda Health System Medical Executive Committee (MEC)
Report to the Quality Professional Services Committee of the Board

Operations:

- Policy and protocol development/implementation
- Nursing leadership engagement and stability: i.e., high turnover/interim for key nursing and education roles

Multiple concerns were conveyed about the low utilization of operating room time in our system and the barriers to scheduling cases. In summary, opportunities exist in Operating Room efficiency and operations which have been elevated to leadership as organizational priorities.

Ethics Committee

The report was presented using the SWOT format.

Strengths

- Multidisciplinary membership
- *All-volunteer* = strong commitment
- Experienced Leadership
- Committed Committee members
- Leaders participation in Regional Ethics
- Ongoing Education, Retreats

Weaknesses

- Add

Opportunities

- Educational outreach
- Policy Development & Collaboration

Threats

- Staffing attrition and turnover
- Constant need for community members
- High number of unrepresented incapacitated patients + rotating social work = delays

Ethics Continuing Issues reported include:

- Unrepresented patient
- Incapacitated by actively resisting
- Choice of Surrogate Decision Maker
- DCD – Should AHS participate? Issue of consent, equity, the death experience for families, allocations of organs, and more

Support is needed from the leadership overseeing the Social Work department to enhance staff training, expand expertise, and increase patient access. Strengthening these areas will directly contribute to improved patient throughput, reduced length of stay, and patient-centered end-of-life care.

Alameda Hospital Medical Executive Committee (MEC)
and
Alameda Health System Medical Executive Committee (MEC)
Report to the Quality Professional Services Committee of the Board

AHS & AH Department of Emergency Medicine Report

Dr. Charlotte Wills, MD provided the annual report highlighting the Department's Strengths, Weaknesses, Opportunities, and Threats. These are aligned with a focus on the Department's Quality and Patient Safety, Structure, and Operations (see attached).

First 6-Months Progress Report

The Chief of Staffs provided a report of the major activities for the period January – June 2025 including credentialing actions, quality and safety updates, process improvement, policy changes, and medical staff concerns or recommendations.

- Guiding Principles: The organized Medical Staff is responsible for the "quality of medical care to patients and for the ethical and professional practices of its members." (AHS Board of Trustees Bylaws)
- National Committee for Quality Assurance (NCQA) Accreditation in Credentialing achieved May 2025, which reflects high standards in credentialing and provider enrollment.
- Participation in The Joint Commission Mock survey
- Credentialing and Privileging volume with an opportunity to better understand the number of voluntary resignations which will be shared with the QPSC in August and the Board of Trustees in September.
- Procedural Innovation Taskforce ensure that necessary credentialing/privileging is aligned with operational infrastructure and the overall mission of AHS
- Enlisted a consultant group to evaluate our existing peer review process, provide best practices to improve the current process.
- Medical Staff engaged in Quality Assurance and Process Improvement (QAPI) governance with the Quality Department
- Monitoring of Quality Objectives and Key Results (OKRs) and Key Performance Indicators (KPIs)
- Emergency Department boarding, hospital acquired infections, readmission rates and mortality indicators
- Committees added to Medical Staff governance (May and June 2025): Clinical Practice Council (CPC), Critical Care Committee, Procedural Sedation Committee, Sepsis Committee and Stroke Committees
- Patient Safety Committee created to oversee Root Cause Analysis
- Standing educational component at monthly MEC meetings.
- The GME Committee oversees the accreditation of physician and dental training programs. ACGME Survey: All training programs were found to be in good standing, with no citations issued during the spring survey. The Addiction Medicine Fellowship

inaugural site visit September 2025, and the Oral and Maxillofacial Surgery Program is preparing for 2026 visit.

- AHS supports millions of dollars in grants awarded to physician researchers for innovative programs that enhance care in the safety net. Future Needs: More infrastructure to support academic research is an identified need and is receiving support from the Executive Operations Team.
- Systemwide Care Coordination: The 'Doc of the Day' has been approved and is anticipated to start in Fall 2025. This role will help identify and coordinate transfers across the system. The Interdisciplinary Rounds dashboard has improved visibility of inpatients ready for discharge; however, securing safe discharge for every patient remains a challenge due to limited community resources. Efforts are underway on a dashboard to provide real-time insight into system-wide bed availability to optimize patient movement.
- The Alameda Hospital Medical Staff has identified facility-specific concerns impacting access, patient care, and operations. i.e., limited availability of specialty consults (Urology), maintenance causing downtime for imaging services (such as MRI and CT), and ensuring the consistent availability of ultrasound on weekends. We are actively working to resolve these matters to enhance patient service.
- Additional work in the coming months includes:
    - Solidify the culture of IPPC as an interdepartmental peer review committee
    - Further define the scope of the Patient Safety Committee
    - Launch of the Procedural Innovation Committee
    - Review and evaluation of department specific OPPE metrics
    - Peer Review Redesign
    - Elections for At-Large Members in December
    - Planning for an in person Annual Meeting and mixer in December

AH Medical Staff

The Medical Executive Committee discussion identified facility-specific concerns impacting access, patient care, and operations, including:

- Limited availability of specialty consults – Urology

D. Quality Reports

BOT Executive Summary: Quality Report
Ana Torres, Vice President of Quality
June 25, 2025

Key Point 1: Four of the eight metrics on the OKR Dashboard met goal or performed better than baseline. Two metrics performed equal to the baseline and two did not meet the goal.

	Performance		
Key Result	**Met goal**	**≥ Baseline**	**Did not meet goal**
Total Patient Harms			✓
Sepsis Mortality (O/E)		= baseline	
Readmission, All Cause			✓
Waitlist Time – New Primary Care	✓		
ED Boarding – Community Hospitals		✓	
ED Boarding- WCHGH		= baseline	
Health-Related Social Needs Assessment Screening (HRSN)		✓	
Likelihood to Recommend		✓	

HARMS

Hospital Acquired Pressure Injuries (HAPI) are the most frequently reported harm. The HAPI events peaked in December but have since declined. The improvement strategy centers around early identification of high-risk patients and rapid implementation of prevention measures.

READMISSIONS

Alameda Hospital and San Leandro Hospital are not meeting the readmission goal. The improvement strategy for readmissions is focused on identifying and addressing the challenges of each hospital. Alameda Hospital readmissions are primarily SNF patients admitted for chronic disease management. San Leandro Hospital readmissions are primarily patients with pain management needs and substance use disorder.

LIKELIHOOD TO RECOMMEND:

The Likelihood to Recommend goal for acute care was not met at any of the hospitals. The improvement plan focuses on addressing responsiveness of staff, leader rounding, the discharge communication process which addresses several patient satisfaction areas, reinforcement of GIFT, and standards of behavior with accompanying customer service in-service training.

Key Point 2: AHS has achieved successes at the individual hospital level.

Improvement Goal = 50% gap closure to the benchmark
Benchmark Goal = CMS 50th percentile; 20% improvement from baseline (HAPI, Behavior Events); national mean (sepsis mortality); 75th percentile (Patient Experience)

Alameda Hospital

- Metrics meeting the benchmark goal: Central line-associated bloodstream infection (CLABSI), MRSA bloodstream infection, C. difficile infection (CDI), Sepsis Mortality
- Metrics meeting the improvement goal: Catheter associated urinary tract infection (CAUTI), Falls with Injury, and ED Likelihood to Recommend
- Metrics improved over the baseline goal: ED Boarding with a 6.7% improvement and Screening for Health-Related Social Needs (HRSN) with a 28% improvement

Highland

- Metrics meeting the benchmark goal: CLABSI
- Metrics meeting the improvement goal: CAUTI, MRSA, CDI, Falls with Injury, Readmissions, HRSN, ED Likelihood to Recommend, and Ambulatory Surgery Likelihood to Recommend
- Metrics improved over the baseline goal: Likelihood to Recommend for Acute care with a 0.4% improvement

San Leandro Hospital

- Metrics meeting the benchmark goal: CLABSI, CAUTI, Behavior Events with Injury, HRSN
- Metrics meeting the improvement goal: CDI, and Ambulatory Surgery Likelihood to Recommend
- Metrics improved over the baseline goal: ED Boarding with a 4.8% improvement and ED Likelihood to Recommend with a 0.5% improvement

John George Hospital

- Metrics meeting the benchmark goal: Behavior Events with Injury

Ambulatory Care

- Metrics meeting the benchmark goal: Behavior Events with Injury
- Metrics meeting the improvement goal: Waitlist time for Primary Care

Key Point 3: There were no self-reported events or regulatory visits for June 2025.

JULY
2025

Regulatory Affairs QPSC Report

- OPEN Session

Nilda Perez – System Director of Regulatory Affairs
ALAMEDA HEALTH SYSTEM

I. Regulatory Events Summary – OPEN Session

A. Site Visits and Complaints

1. No site visits in June 2025.

B. CDPH Self-Reported Events

1. No CDPH Self-Reported Events in June 2025.

C. Joint Commission Complaints

1. No Joint Commission Complaints in June 2025.

D. Joint Commission Sentinel Events

1. No Joint Commission Sentinel Events reported in June 2025.

E. Joint Commission Activity

1. Alameda Hospital Primary Stroke Certification Intracycle Call June 20, 2025.

F. AHS Licensing Projects

1. No active licensing projects currently.

QPSC BOT Executive Summary: Post-Acute Quality Report
Richard Espinoza, NHA, CAO Post-Acute Services
7/23/25

Key Point 1: **Quality Star ratings – Overall and Quality Measures:**
Strategic Plan for 2024-2025 was for post-acute SNF/SA sites to maintain 5 star CMS ratings
All Skilled Nursing Facilities/Sub-Acute (SNF/SA) sites 5-star CMS rated for Overall Quality – achieved

Fairmont continues with 5 stars in every CMS category – the highest outcome possible.

The top 10% of skilled nursing facilities in the United States receive a 5-star rating from the Centers for Medicare and Medicaid Services (CMS)

Key Point 2: **June CMS ratings:**
All SNF/SA overall 5 stars rated

Key Point 3: **2025-2026 Focus Metrics:**
Based on CMS metric changes and identified opportunities at the sites

Key Point 4: **CDPH/CMS visits:**
Annual AHS self-reports/CDPH visits: 26 (not including surveys)
25 no findings and 1 finding outcome – POC accepted and cleared

Key Point 5: **CDPH/CMS survey outcomes:**
South shore, Sub-Acute, Park Bridge, Fairmont survey outcomes – all outperformed state and federal averages

St. Rose passed State, Federal, and Life Safety CDPH/CMS surveys – outperformed state and federal averages

Key Point 6: **Newsweek: America's Best Nursing Homes**
South shore, Sub-Acute and Park Bridge named in Newsweek America's Best Nursing Homes – 4th time being recognized

Key Point 7: **Registry Reduction:**
Fairmont, South shore 100% out of registry utilization in 2025. Park Bridge 96% out of registry utilization as of June 2025 and their goal is to be 100% out by September 1st, 2025. ARU, Sub-Acute, St. Rose, do not utilize registry

Key Point 8: **Miscellaneous items:**

- **Post-Acute billing team (SNF/SA units)**
  AR days: **July 2024**: 70.3 days **June 2025**: 66 day **Goal was**: 62 days

- **Rehabilitation**: standardized work around scheduling, authorizations, registration workflows, for outpatient services
- Enhancements for post operative orthopedics and hand surgery, acute rehabilitation outpatient care
- Registry reduction plan in place – 8 registry for rehabilitation team in use systemwide – covering maternity leave, open positions, medical leave – Goal is to eliminate registry use in 2025-2026 year

- **Palliative care in post-acute**:
- Pilot at Fairmont SNF with Palliative care team
- Chaplain and Physicians 2 times a week
- Expansion to other AHS post-acute SNF/SA units pending hiring – some consults already performed
- Great collaboration between Palliative care team and post-acute teams
- 50% of Fairmont SNF residents have received a palliative care consult – leads to better outcomes, pain management, and patient comfort/satisfaction

E. QPSC Metric Selection and Goal Setting Approval

Quality OKR Metric Proposal FY2026

QPSC

July 23rd , 2025

Objectives & Key Results (OKRs)

vs.

Key Performance Indicators (KPIs) & Metrics

Objectives

- Aspirational goals tied to organizational mission and vision
  Who we are, who we serve
- Bring "life" to the organizational strategic plan
  Where we're headed
- Inspiring and memorable

Key Results

- ***Critical milestones*** which measure progress toward objectives
- Generally no more than 3-5KRs per objective

Key Performance Indicator

- Data reflecting how the system is working
- key *domain-specific process and outcome metrics*
- Organizations can have hundreds across domains
- KPIs don't necessarily provide broader context for overall Organizational Objectives

Metric

Any measure of something

The difference between KPIs and OKRs. https://www.whatmatters.com/resources/difference-between-okr-kpi

ALAMEDA HEALTH SYSTEM

Quality Care

Pillar Definition:

AHS provides Safe, Timely, Effective, Efficient, Equitable and Patient-Centered care that is accessible to all.

Strategic Objective: Safe place to receive exceptional and compassionate care

Strategic Key Results
Leapfrog Hospital Grades: Target A-B
CMS Hospital STAR Ratings : Shadow Metric Year 1 and 2
CMS Post-Acute STAR Ratings : Maintain 5 STARS
CDPH Quality Incentive Program : Optimal Performance
Quality Perception: Improve staff perception of quality of care

Pocket

Fiscal Year 2026 Quality OKR Proposal: Metric Definitions

OBJECTIVES	KEY RESULTS	Definition	Strategic Key Results Link	Recommendation
Safe Care - Caring, Healing, Teaching All				
Provide safe care	Total Patient Harms	The number of potential health-care acquired patient harms Includes: CLABSI, CAUTI, MRSA BSI, C-Diff, SSI, Patient Falls with injuries, Hospital Acquired Pressure Injuries and Behavior Events that result in Injury	Leapfrog, CMS Star Rating. HAC Penalty, QIP	**Revise** - Reportable HAPIs, Focus 6 Surgical Categories for SSI (Colon, C-Section, Gallbladder, Hysterectomy, Spinal Fusion, Small Bowel)
	Sepsis Bundle	Compliance to Sepsis early recognition and intervention guidelines. This is an "all-or-nothing" measure, meaning all elements must be met to receive credit. Follows CMS/TJC SEP 1 Definition	CMS Star Rating	**Add**
	Sepsis Mortality O/E Ratio	The observed to expected ratio is a comparison of the actual number of sepsis-related deaths in a hospital (observed) to the predicted number of deaths (expected).	CMS Star Rating	**Keep**
Timely, Effective, and Efficient Care				
Promote wellbeing	All Cause 30-day readmission rate	Percentage of inpatient acute med-surg encounters, regardless of payer type, with an unplanned readmission to any AHS facility within 30 days for any cause for acute care inpatients	CMS Star Rating, Readmission Penalty	**Keep**
Provide accessible care	Waitlist time - New Specialty Referral	The amount of days between when a new patient to AHS requests/referred for an initial specialty care appointment to the day of appointment.	Ambulatory Access	**Revise** % of Specialty Clinics at Goal
	ED Boarding Time for Admitted Patients Community/HGH	Median time from Decision to Admit to departure from the emergency department for admitted patients.	CMS Star Rating	**Keep**

Fiscal Year 2026 Quality OKR Proposal : Metric Definitions

OBJECTIVES	KEY RESULTS	Definition	Strategic Key Results Link	Recommendation
Equitable Care				
Serving all: ~~Deliver equitable care~~ Deliver Whole Person Care	Health-related Social Needs Assessment Completed on Hospital Inpatient and Outpatient Encounters	The percentage of hospital inpatient and hospital outpatient encounters where the patient is screened for social determinants of health: food insecurity, housing, transportation, safety and utilities	Process Readmissions Link Stewardship: Grow and optimize resources for the patient care continuum to meet the community need	**Revise** Expand to Hospital Based Outpatient Encounters (ED, Same Day Surgery, Imaging, Testing) **Add** 2nd Metric Screening Positivity Rate
Patient-Centered Care				
Be the most welcoming system to receive care	Likelihood to recommend care composite	Percentage of patients who would recommend AHS (includes rehab, acute, ambulatory, ED, outpatient surgery, dental, radiology)	Leapfrog, Star Rating	**Keep**

Agenda Item D: OKRS

Alameda Hospital FY 2025 Detailed Quality OKR and KPI Dashboard

Vision: Alameda Health System will be recognized as a world-class patient and family centered system of care that promotes wellness, eliminates disparities and optimized the health of our diverse communities.

Safe Care - Caring, Healing, Teaching All			Performance			FY25 Goals		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
Provide safe care	Eliminate Patient Harms	Total Patient Harms	2	65	38	28	22	
		CLABSI # Events/SIR	0/0	0/0	0/0	0/0.378	1/0.756	
		CAUTI # Events/SIR	0/0	1/0.71	0/0	0/0.323	1/0.646	
		MRSA # Events/SIR	Pending/0	0/0	0/0	0/0.397	0/0.793	
		C. Difficile # Events/SIR	Pending/0	2/0.39	8/81.48	5/0.944	2/0.417	
		SSI # Events/SIR	Pending/0	1/1.32	0/0	0/0.38	0/0.756	
		Falls with Injury/% Per 1000 Days	1/1.04	9/0.53	13/0.94	9/0.71	6/0.49	
		HAPI #/% per 1000 Discharges	1/4.673	45/19.62	15/4.98	11/3.89	10/3.46	
		Behavior Events with Physical Injury	0/0	7/0.62	2/0.03	1/0.13	1/0.11	
		Serious Safety Events (F or Greater)	0	0	0			
	Reduce Mortality from Sepsis	Sepsis Mortality Observed:Expected & Total Deaths	NA	1.03	1.04		1.04	
		Bundle Compliance Sepsis Early Management	66.67%	73.81%	51.10%			
	Embed Critical Behaviors	Hand Hygiene Compliance	76.10%	85.14%	83.30%			

Fiscal Year Starts in July 1 and Ends June 30

FY25 YTD is results from July 2024 to Apr 2025

Timely, Effective, and Efficient Care			Performance			FY25 Goals		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
Promote wellbeing	Provide the right care at the right time	All Cause 30-Day Readmission Rate	13.25%	15.76%	14.42%	12.46%	11.12%	
Provide accessible care	Minimize Time Spent Waiting for our Patients	ED Boarding Time for Admitted Patients	2:37	3:02	3:15	2:20	1:30	
Equitable Care			Performance			FY25 Goals		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
Serving all: Deliver equitable care	Health-related social needs recognized and addressed	Health-related social needs assessment completed on inpatients	63.80%	49.50%	38.67%	75%	90%	
		Health-related social needs referrals placed	NA	NA	NA	Pending	Pending	
Patient-Centered Care			Performance			FY25 Goals		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
Be the most welcoming system to receive care	Optimize performance regarding patient experience	Likelihood to recommend Acute	49.30%	60.11%	64.62%	65.91%	77.80%	
		Likelihood to recommend ED	61.90%	65.08%	58.92%	60.02%	70.10%	
		Communication with Nurses	66.03%	67.39%	72.89%	74.35%	76.41%	
		Communication with Providers	80.28%	75.23%	79.13%	80.71%	83.40%	

Fiscal Year Starts in July 1 and Ends June 30

FY25 YTD is results from July 2024 to Apr 2025

Fiscal Year 2025

OKR Metric Definitions for QPSC

Metric	Definition	GOAL	
		Improvement	Benchmark
Patient Harm	The number of potential health-care acquired patient harms Includes: CLABSI, CAUTI, MRSA BSI, C-Diff, SSI for Acute Med-Surg/Critical Care, and Patient Falls with injuries, Hospital Acquired Pressure Injuries and Behavior Events that result in Injury for all areas (practically, not inclusive of ambulatory)	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile NDNQI 50th Percentile
CLABSI # Events/ SIR	A primary bloodstream infection (that is, there is no apparent infection at another site) that develops in a patient with a central line in place . #: Number of infections that occurred SIR: Standardized Infection Ratio compares the actual number of infections to the predicted number of infections. The predicted number is risk adjusted. Results less 1 are desirable	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile
CAUTI # Events/ SIR	an infection of the urinary tract caused by a tube (urinary catheter) that has been placed to drain urine from the bladder. #: Number of infections that occurred SIR: Standardized Infection Ratio compares the actual number of infections to the predicted number of infections. The predicted number is risk adjusted. Results less 1 are desirable	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile
MRSA # Events/ SIR	Potential hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA) staph infection that is difficult to treat because of resistance to some antibiotics. #: Number of infections that occurred SIR: Standardized Infection Ratio compares the actual number of infections to the predicted number of infections. The predicted number is risk adjusted. Results less 1 are desirable	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile
C. Difficile # Events/ SIR	Potential hospital acquired infection that causes diarrhea and colitis (an inflammation of the colon). #: Number of infections that occurred SIR: Standardized Infection Ratio compares the actual number of infections to the predicted number of infections. The predicted number is risk adjusted. Results less 1 are desirable	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile
SSI # Events/ SIR	an infection that occurs after surgery in the part of the body where the surgery took place. Excludes superficial infections. Attributed to date of procedure. #: Number of infections that occurred attributed to month procedure performed SIR: Standardized Infection Ratio compares the actual number of infections to the predicted number of infections. The predicted number is risk adjusted. Results less 1 are desirable	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile
Falls with Injury/ # % Per 1000 Days	Patient Fall reported via Midas Safety Alert. # of Events / Rate: Number of events divided by number of patient days times 1000	50% gap reduction to the 50th Percentile	NDNQI 50th Percentile
HAPI #/ % per 1000 DCs	Hospital Acquired Pressure Ulcers reported via Midas Safety Alert. # of Events / Rate: Number of events divided by number of patient discharges times 1000	10% improvement as compared to Fiscal Year 2024	20% improvement as compared to Fiscal Year 2024
Behavior Events with Physical Injury	Behavior events that resulted in physicial injury via Midas Safety Alerts # of Events/Rate: Number of events divided by number of patient days times 1000	10% improvement as compared to Fiscal Year 2024	20% improvement as compared to Fiscal Year 2024
Serious Safety Events (F or Greater)			

Fiscal Year 2025

OKR Metric Definitions for QPSC

Metric	Definition	GOAL	
		Improvement	Benchmark
Sepsis Mortality O/E Ratio	The observed to expected (O:E) sepsis mortality ratio is a comparison of the actual number of sepsis-related deaths in a hospital (observed) to the predicted number of deaths (expected). Performance is considered better than expected if the O:E ratio is less than 1, and worse than expected if the ratio is greater than 1. A lower O:E ratio indicates that more people are surviving conditions that would otherwise be fatal.	NA	1.04 National Mean per Vizient
Bundle Compliance Sepsis Early Management	A set of guidelines that hospitals use to manage patients with severe sepsis or septic shock. The guidelines focus on early recognition and intervention to save lives and limbs. This is an "all-or-nothing" measure, meaning that hospitals must adhere to all elements of the bundle to receive credit. Follows CMS/TJC SEP 1 Definition		
Hand Hygiene Compliance	Hand hygiene is a leading way to reduce the spread of pathogens in healthcare settings. It includes: Washing hands with soap and water and Using an antiseptic handrub. Hand hygiene compliance is the percentage of times that a person performs hand hygiene when an opportunity arises. It's calculated by dividing the number of hand hygiene actions performed by the total number of opportunities.		
All-cause 30 day Readmissions Rate	Percentage of inpatient acute med-surg encounters, regardless of payer type, with an unplanned readmission to any AHS facility within 30 days for any cause among encounters for acute care inpatients with a principal discharge diagnosis/procedure for a clinical classification category in the Cardiorespiratory, Cardiovascular, Medicine, Neurology, or Surgery/Gynecology cohort. *Note:* This measure approximates, but likely does not match, the value of the corresponding CMS readmission measure.	50% gap reduction to the 50th Percentile CMS Hospital Compare	50th Percentile CMS Hospital Compare
NTSV Cesarean Section Rate	he NTSV C-section rate is the percentage of live babies born to women in their first pregnancy who meet the following criteria: Born at or after 37 weeks gestation Singleton (no twins or more) In the vertex presentation (no breech or transverse positions)		
ED Boarding Time Time in ED from Decision to Admit to Inpatient Bed	Median time from Decision to Admit to departure from the emergency department for admitted patients. Decision to Admit = First Admit Disposition Admit = Time patient admitted to Inpatient Unit	2:20 Community Hospitals: 50% gap closure to pre=pandemic performance 8:30 Highland: 50% gap closure to TJC benchmark	1:30 Community Hospitals: Pre-pandemic Performance 4:00 Highland: TJC guidance for max boarding time
Rate of Inpatients screened for health-related social needs (food, housing, transportation, safety, utilities) ↑	The percentage of inpatient acute medical/surgical admissions where the patient is screened for social determinents of health: food insecurity, housing, transportation, safety and utilites	75% Internal Benchmark: Best Performing Campus rate for FY24	90% Internal Benchmark: Monthly Rate achieve by Best Performing Campus
Health-related social needs referrals placed	A "health-related social needs referral" means directing a patient to a community service or organization that can address social issues impacting their health, such as food insecurity, housing instability, lack of transportation, or financial hardship, identified through a screening process within a healthcare setting; essentially, referring a patient to support that can help address social factors that could be affecting their health outcomes.	TBD	TBD
Acute: Rate of patients who reported they would “definitely” recommend AHS	Percentage of discharged inpatients who would recommend AHS	2% improvement as compared to Fiscal Year 2024	75th Percentile per Press Ganey
Same Day Surgery:Rate of patients who reported they would “definitely” recommend AHS	Percentage of same day surgery patients who would recommend AHS	2% improvement as compared to Fiscal Year 2024	50th Percentile per Press Ganey

Fiscal Year 2025

OKR Metric Definitions for QPSC

Metric	Definition	GOAL	
		Improvement	Benchmark
Emergency: Rate of patients who reported they would “definitely” recommend AHS	Percentage of Emergency patients who would recommend AHS	2% improvement as compared to Fiscal Year 2024	50th Percentile per Press Ganey
Communication with Nurses	A domain of HCAHPS which measures patients' perceptions of how well patients feel that their nurses: explained things clearly, listened carefully, and treated the patient with courtesy and respect. Percent of surveyed Inpatient discharges where patient response was highest of the scale	2% improvement as compared to Fiscal Year 2025	50h Percentile per Press Ganey
Communication with Providers	A domain of HCAHPS which measures patients' perceptions of how well patients feel that their provider(s): explained things clearly, listened carefully, and treated the patient with courtesy and respect. Percent of surveyed Inpatient discharges where patient response was highest of the scale	2% improvement as compared to Fiscal Year 2026	Per Press Ganey Community Hospitals: 75th Percentile Highland Hospital: 90th Percentile

Ambulatory FY 2025 Detailed Quality OKR and KPI Dashboard

Vision: Alameda Health System will be recognized as a world-class patient and family centered system of care that promotes wellness, eliminates disparities and optimized the health of our diverse communities.

Safe Care - Caring, Healing, Teaching All			Performance			FY25 Goals		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
Provide safe care	Eliminate Patient Harms	Total Patient Harms	0	0	2	1	0	
		Behavior Events with Physical Injury	0/	0/0	2	1	0	
		Serious Safety Events (F or Greater)	0	1	0	1	0	
	Embed Critical Behaviors	Hand Hygiene Compliance	84.30%	81.25%	80.40%	88.44%	90%	
Timely, Effective, and Efficient Care			**Performance**			**FY25 Goals**		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
Promote wellbeing	Provide the right care at the right time	All Cause 30-Day Readmission Rate	6.88%	12.36%	12.05%	11.56%	11.12%	
		MyChart Activation Rate	0.00%	30.22%	27.00%			
	Find and treat conditions early	Breast Cancer Screening	59.42%		54.88%	53.99%	62.67%	
		Cervical Cancer Screening	44.61%		41.94%	50.85%	66.48%	
		Colorectal Cancer Screening	60.50%		61.35%	60.04%	61.32%	
	Achieve the best health outcomes	Glycemic status assessment of patients with diabetes	31.32%		32.00%	32.83%	29.44%	
		Controlling High Blood Pressure	63.40%		63.40%	62.18%	72.22%	
		Child and Adolescent Well-Care Visits	49.46%		43.96%	45.80%	61.15%	

Fiscal Year Starts in July 1 and Ends June 30

FY25 YTD is results from July 2024 to Apr 2025

Timely, Effective, and Efficient Care (continued)			Performance			FY25 Goals		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
	Minimize Time Spent Waiting for our Patients	TNAA Primary Care - Return	6	6	10	10	2	
		TNAA Specialty Care -Return	1	1	7	15	2	
		Waitlist time - Primary Care Review	62	62	94	71	30	
		Waitlist time - Specialty Care	17	17	36	30	N/A	

Equitable Care			Performance			FY25 Goals		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
Serving all: Deliver equitable care	Health-related social needs recognized and addressed	Health-related social needs referrals placed	0	NA	NA			

Patient-Centered Care			Performance			FY25 Goals		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
Be the most welcoming system to receive care	Optimize performance regarding patient experience	Likelihood to recommend (Dental)	64.62%	62.40%	61.05%	62.27%	63.49%	
		Likelihood to recommend (Primary/Specialty)	73.77%	72.88%	75.93%	75.16%	94.40%	
		Communication with Care Provider (Primary/Specialty)	75.28%	73.75%	76.48%	76.28%	78.01%	

Fiscal Year Starts in July 1 and Ends June 30

FY25 YTD is results from July 2024 to Apr 2025

Highland FY 2025 Detailed Quality OKR and KPI Dashboard

Vision: Alameda Health System will be recognized as a world-class patient and family centered system of care that promotes wellness, eliminates disparities and optimized the health of our diverse communities.

Safe Care - Caring, Healing, Teaching All			Performance			FY25 Goals		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
Provide safe care	Eliminate Patient Harms	Total Patient Harms	18	183	173	145	119	
		CLABSI # Events/SIR	Pending /0	0/0	7/0.775	6/0.766	6/0.756	
		CAUTI # Events/SIR	1/0	7/1.29	13/1.54	9/1.093	5/0.646	
		MRSA # Events/SIR	Pending/0	2/0.97	3/1.01	2/1.034	1/0.793	
		C. Difficile # Events/SIR	Pendingq/0	13/0.65	20/0.77	15/0.599	10/0.417	
		SSI # Events/SIR	Pending/0	33/2.87	24/1.68	18/1.13	12/0.756	
		Falls with Injury/% Per 1000 Days	5/0.82	31/0.44	35/0.6	32/0.56	30/0.52	
		HAPI #/% per 1000 Discharges	9/10.022	72/7.72	46/3.95	41/3.55	36/3.16	
		Behavior Events with Physical Injury	3/0.61	27/0.56	27/0.51	22/0.39	19/0.34	
		Serious Safety Events (F or Greater)	0	9	6			
	Reduce Mortality from Sepsis	Sepsis Mortality Observed:Expected & Total Deaths	NA	1.14	1.07		1.04	
		Bundle Compliance Sepsis Early Management	46.15%	56.52%	46.30%			
	Embed Critical Behaviors	Hand Hygiene Compliance	91.20%	88.90%	91.05%			
Fiscal Year Starts in July 1 and Ends June 30					FY25 YTD is results from July 2024 to Apr 2025			

Highland FY 2025 Detailed Quality OKR and KPI Dashboard

Timely, Effective, and Efficient Care			Performance			FY25 Goals		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
Promote wellbeing	Provide the right care at the right time	All Cause 30-Day Readmission Rate	9.78%	11.39%	12.14%	11.36%	11.12%	
	Achieve the best health outcomes	NTSV Cesarean Section Rate	NA	23.00%	22.60%			
Provide accessible care	Minimize Time Spent Waiting for our Patients	ED Boarding Time for Admitted Patients	14:29	13:13	13:05	8:32	4:00	
Equitable Care			Performance			FY25 Goals		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
Serving all: Deliver equitable care	Health-related social needs recognized and addressed	Health-related social needs assessment completed on inpatients	88.20%	76.00%	62.31%	75%	90%	
		Health-related social needs referrals placed	NA	NA	NA	Pending	Pending	
Patient-Centered Care			Performance			FY25 Goals		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
Be the most welcoming system to receive care	Optimize performance regarding patient experience	Likelihood to recommend Acute	79.60%	75.06%	74.75%	76.25%	77.80%	
		Likelihood to recommend ED	66.15%	57.04%	52.97%	54.03%	70.10%	
		Likelihood to recommend Amb Surg	81.48%	81.42%	77.82%	79.43%	86.00%	
		Communication with Nurses	77.42%	73.45%	74.53%	76.02%	76.41%	
		Communication with Providers	83.93%	82.60%	83.40%	85.07%	85.93%	
Fiscal Year Starts in July 1 and Ends June 30			FY25 YTD is results from July 2024 to Apr 2025					

Fiscal Year 2025

OKR Metric Definitions for QPSC

Metric	Definition	GOAL	
		Improvement	Benchmark
Patient Harm	The number of potential health-care acquired patient harms Includes: CLABSI, CAUTI, MRSA BSI, C-Diff, SSI for Acute Med-Surg/Critical Care, and Patient Falls with injuries, Hospital Acquired Pressure Injuries and Behavior Events that result in Injury for all areas (practically, not inclusive of ambulatory)	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile NDNQI 50th Percentile
CLABSI # Events/ SIR	A primary bloodstream infection (that is, there is no apparent infection at another site) that develops in a patient with a central line in place . #: Number of infections that occurred SIR: Standardized Infection Ratio compares the actual number of infections to the predicted number of infections. The predicted number is risk adjusted. Results less 1 are desirable	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile
CAUTI # Events/ SIR	an infection of the urinary tract caused by a tube (urinary catheter) that has been placed to drain urine from the bladder. #: Number of infections that occurred SIR: Standardized Infection Ratio compares the actual number of infections to the predicted number of infections. The predicted number is risk adjusted. Results less 1 are desirable	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile
MRSA # Events/ SIR	Potential hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA) staph infection that is difficult to treat because of resistance to some antibiotics. #: Number of infections that occurred SIR: Standardized Infection Ratio compares the actual number of infections to the predicted number of infections. The predicted number is risk adjusted. Results less 1 are desirable	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile
C. Difficile # Events/ SIR	Potential hospital acquired infection that causes diarrhea and colitis (an inflammation of the colon). #: Number of infections that occurred SIR: Standardized Infection Ratio compares the actual number of infections to the predicted number of infections. The predicted number is risk adjusted. Results less 1 are desirable	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile
SSI # Events/ SIR	an infection that occurs after surgery in the part of the body where the surgery took place. Excludes superficial infections. Attributed to date of procedure. #: Number of infections that occurred attributed to month procedure performed SIR: Standardized Infection Ratio compares the actual number of infections to the predicted number of infections. The predicted number is risk adjusted. Results less 1 are desirable	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile
Falls with Injury/ # % Per 1000 Days	Patient Fall reported via Midas Safety Alert. # of Events / Rate: Number of events divided by number of patient days times 1000	50% gap reduction to the 50th Percentile	NDNQI 50th Percentile
HAPI #/ % per 1000 DCs	Hospital Acquired Pressure Ulcers reported via Midas Safety Alert. # of Events / Rate: Number of events divided by number of patient discharges times 1000	10% improvement as compared to Fiscal Year 2024	20% improvement as compared to Fiscal Year 2024
Behavior Events with Physical Injury	Behavior events that resulted in physicial injury via Midas Safety Alerts # of Events/Rate: Number of events divided by number of patient days times 1000	10% improvement as compared to Fiscal Year 2024	20% improvement as compared to Fiscal Year 2024
Serious Safety Events (F or Greater)			

Fiscal Year 2025

OKR Metric Definitions for QPSC

Metric	Definition	GOAL	
		Improvement	Benchmark
Sepsis Mortality O/E Ratio	The observed to expected (O:E) sepsis mortality ratio is a comparison of the actual number of sepsis-related deaths in a hospital (observed) to the predicted number of deaths (expected). Performance is considered better than expected if the O:E ratio is less than 1, and worse than expected if the ratio is greater than 1. A lower O:E ratio indicates that more people are surviving conditions that would otherwise be fatal.	NA	1.04 National Mean per Vizient
Bundle Compliance Sepsis Early Management	A set of guidelines that hospitals use to manage patients with severe sepsis or septic shock. The guidelines focus on early recognition and intervention to save lives and limbs. This is an "all-or-nothing" measure, meaning that hospitals must adhere to all elements of the bundle to receive credit. Follows CMS/TJC SEP 1 Definition		
Hand Hygiene Compliance	Hand hygiene is a leading way to reduce the spread of pathogens in healthcare settings. It includes: Washing hands with soap and water and Using an antiseptic handrub. Hand hygiene compliance is the percentage of times that a person performs hand hygiene when an opportunity arises. It's calculated by dividing the number of hand hygiene actions performed by the total number of opportunities.		
All-cause 30 day Readmissions Rate	Percentage of inpatient acute med-surg encounters, regardless of payer type, with an unplanned readmission to any AHS facility within 30 days for any cause among encounters for acute care inpatients with a principal discharge diagnosis/procedure for a clinical classification category in the Cardiorespiratory, Cardiovascular, Medicine, Neurology, or Surgery/Gynecology cohort. *Note:* This measure approximates, but likely does not match, the value of the corresponding CMS readmission measure.	50% gap reduction to the 50th Percentile CMS Hospital Compare	50th Percentile CMS Hospital Compare
NTSV Cesarean Section Rate	he NTSV C-section rate is the percentage of live babies born to women in their first pregnancy who meet the following criteria: Born at or after 37 weeks gestation Singleton (no twins or more) In the vertex presentation (no breech or transverse positions)		
ED Boarding Time Time in ED from Decision to Admit to Inpatient Bed	Median time from Decision to Admit to departure from the emergency department for admitted patients. Decision to Admit = First Admit Disposition Admit = Time patient admitted to Inpatient Unit	2:20 Community Hospitals: 50% gap closure to pre=pandemic performance 8:30 Highland: 50% gap closure to TJC benchmark	1:30 Community Hospitals: Pre-pandemic Performance 4:00 Highland: TJC guidance for max boarding time
Rate of Inpatients screened for health-related social needs (food, housing, transportation, safety, utilities) ↑	The percentage of inpatient acute medical/surgical admissions where the patient is screened for social determinents of health: food insecurity, housing, transportation, safety and utilites	75% Internal Benchmark: Best Performing Campus rate for FY24	90% Internal Benchmark: Monthly Rate achieve by Best Performing Campus
Health-related social needs referrals placed	A "health-related social needs referral" means directing a patient to a community service or organization that can address social issues impacting their health, such as food insecurity, housing instability, lack of transportation, or financial hardship, identified through a screening process within a healthcare setting; essentially, referring a patient to support that can help address social factors that could be affecting their health outcomes.	TBD	TBD
Acute: Rate of patients who reported they would “definitely” recommend AHS	Percentage of discharged inpatients who would recommend AHS	2% improvement as compared to Fiscal Year 2024	75th Percentile per Press Ganey
Same Day Surgery:Rate of patients who reported they would “definitely” recommend AHS	Percentage of same day surgery patients who would recommend AHS	2% improvement as compared to Fiscal Year 2024	50th Percentile per Press Ganey

Fiscal Year 2025

OKR Metric Definitions for QPSC

Metric	Definition	GOAL	
		Improvement	Benchmark
Emergency: Rate of patients who reported they would “definitely” recommend AHS	Percentage of Emergency patients who would recommend AHS	2% improvement as compared to Fiscal Year 2024	50th Percentile per Press Ganey
Communication with Nurses	A domain of HCAHPS which measures patients' perceptions of how well patients feel that their nurses: explained things clearly, listened carefully, and treated the patient with courtesy and respect. Percent of surveyed Inpatient discharges where patient response was highest of the scale	2% improvement as compared to Fiscal Year 2025	50h Percentile per Press Ganey
Communication with Providers	A domain of HCAHPS which measures patients' perceptions of how well patients feel that their provider(s): explained things clearly, listened carefully, and treated the patient with courtesy and respect. Percent of surveyed Inpatient discharges where patient response was highest of the scale	2% improvement as compared to Fiscal Year 2026	Per Press Ganey Community Hospitals: 75th Percentile Highland Hospital: 90th Percentile

John George FY 2025 Detailed Quality OKR and KPI Dashboard

Vision: Alameda Health System will be recognized as a world-class patient and family centered system of care that promotes wellness, eliminates disparities and optimized the health of our diverse communities.

Safe Care - Caring, Healing, Teaching All			Performance			FY25 Goals		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
Provide safe care	Eliminate Patient Harms	Total Patient Harms	5	60	68	61	54	P. Espeseth R. Delaney
		Falls with Injury/% Per 1000 Days	0/0	13/0.59	9/0.68	8	7	R. Delaney
		Behavior Events with Physical Injury	5/2.17	47/2.12	59/2.15	53	47	P. Espeseth R. Delaney
		Serious Safety Events (F or Greater)	0	0	0	0	0	P. Espeseth R. Delaney
Patient-Centered Care			**Performance**			**FY25 Goals**		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
Be the most welcoming system to receive care	Optimize performance regarding patient experience	Overall Rating of Care	52.38%	57.01%	61.60%	62.83%	68.50%	P. Espeseth R. Delaney

Fiscal Year Starts in July 1 and Ends June 30

FY25 YTD is results from July 2024 to Performance

Fiscal Year 2025

OKR Metric Definitions for QPSC

Metric	Definition	GOAL	
		Improvement	Benchmark
Total Patient Harms	The number of potential health-care acquired patient harms Includes: Patient Falls with injuries, H Behavior Events that result in Injury	10% reduction compared to FY24 overall	20% reduction compared to FY24 overall
Falls with Injury/% Per 1000 Days	Patient Fall reported via Midas Safety Alert. # of Events / Rate: Number of events divided by number of patient days times 1000	10% reduction compared to FY24 overall	20% reduction compared to FY24 overall
Behavior Events with Physical Injury	Behavior events that resulted in physicial injury via Midas Safety Alerts # of Events/Rate: Number of events divided by number of patient days times 1000	10% reduction compared to FY24 overall	20% reduction compared to FY24 overall
Serious Safety Events (F or Greater)			
Overall Rating of Care	A question on the Behavioral Health Dashboard which measures patients' perceptions of how well patients feel that their overall care experience Percent of surveyed discharges where patient response was highest of the scale	2% improvement over FY24 score	50th Percentile

FY 2025 QPSC OKR Dashboard

Vision: Alameda Health System will be recognized as a world-class patient and family centered system of care that promotes wellness, eliminates disparities and optimizes the health of our diverse communities.

Safe Care - Caring, Healing, Teaching All		Performance			Goals		
OBJECTIVES	KEY RESULTS	Apr 2025	FY25 YTD	FY2024 Actual	Improvement	Benchmark	Accountable Leaders
Provide safe care	Total Patient Harms*	33	434	410	353	293	R. Lofton, E. Mahler
	Sepsis Mortality O/E Ratio	0.72	1.05	1.05		1.04	R. Lofton, E. Mahler
Timely, Effective, and Efficient Care							
OBJECTIVES	KEY RESULTS	Apr 2025	FY25 YTD	FY2024 Actual	Improvement	Benchmark	Accountable Leaders
Promote wellbeing	All Cause 30-day readmission rate	11.69%	12.44%	12.05%	11.56%	11.12%	D. Littlepage, E. Mahler
Provide accessible care	Waitlist time - New Primary Care Adult	62	62	94	71	30	T. Fitzgerald-Shaw, P. Mack
	ED Boarding Time for Admitted Patients Community Hospital	3:10	2:58	3:10	2:20	1:30	R. Lofton, A.Wu
	ED Boarding Time for Admitted Patients Highland	14:29	13:03	13:05	8:30	4:00	R. Lofton, A. Wu
Equitable Care							
OBJECTIVES	KEY RESULTS	Apr 2025	FY25 YTD	FY2024 Actual	Improvement	Benchmark	Accountable Leaders
Serving all: Deliver equitable care	Health-related Social Needs Assessment Completed on Inpatients	84.50%	74.50%	64.58%	75.00%	90.00%	R. Lofton
Patient-Centered Care							
OBJECTIVES	KEY RESULTS	Apr 2025	FY25 YTD	FY2024 Actual	Improvement	Benchmark	Accountable Leaders
Be the most welcoming system to receive care	Likelihood to recommend care composite	80.02%	77.74%	77.24%	78.28%	79.16%	R. Lofton, A. Ng

Fiscal Year Starts in July 1 and Ends June 30

FY25 YTD is results from July 2024 to FY25YTD

* AHS' ultimate goal is Zero Hospital Acquired Harm

Fiscal Year 2025

OKR Metric Definitions for QPSC

Metric	Definition	GOAL	
		Improvement	Benchmark
Patient Harm	The number of potential health-care acquired patient harms Includes: CLABSI, CAUTI, MRSA BSI, C-Diff, SSI for Acute Med-Surg/Critical Care, and Patient Falls with injuries, Hospital Acquired Pressure Injuries and Behavior Events that result in Injury for all areas (practically, not inclusive of ambulatory)	353 50% gap reduction to the 50th Percentile	293 NHSN 2022 50th Percentile
Sepsis Mortality O/E Ratio	The observed to expected (O:E) sepsis mortality ratio is a comparison of the actual number of sepsis-related deaths in a hospital (observed) to the predicted number of deaths (expected). Performance is considered better than expected if the O:E ratio is less than 1, and worse than expected if the ratio is greater than 1. A lower O:E ratio indicates that more people are surviving conditions that would otherwise be fatal.	NA	1.04 National Mean per Vizient
All-cause 30 day Readmissions Rate	Percentage of inpatient acute med-surg encounters, regardless of payer type, with an unplanned readmission to any AHS facility within 30 days for any cause among encounters for acute care inpatients with a principal discharge diagnosis/procedure for a clinical classification category in the Cardiorespiratory, Cardiovascular, Medicine, Neurology, or Surgery/Gynecology cohort. *Note:* This measure approximates, but likely does not match, the value of the corresponding CMS readmission measure.	11.56% 50% gap reduction to the 50th Percentile CMS Hospital Compare	11.12% 50th Percentile CMS Hospital Compare
Waitlist time - New Primary Care Adult	The amount of days between when a new patient to AHS requests an intial primary care appointment to the day of appointment.	84 Days 25% Reduction	30 Days Eliminates waitlist as most clinics schedule up to 30 days out
ED Boarding Time Time in ED from Decision to Admit to Inpatient Bed	Median time from Decision to Admit to departure from the emergency department for admitted patients. Decision to Admit = First Admit Disposition Admit = Time patient admitted to Inpatient Unit	2:20 Community Hospitals: 50% gap closure to pre=pandemic performance 8:30 Highland: 50% gap closure to TJC benchmark	1:30 Community Hospitals: Pre-pandemic Performance 4:00 Highland: TJC guidance for max boarding time
Rate of Inpatients screened for health-related social needs (food, housing, transportation, safety, utilities) ↑	The percentage of inpatient acute medical/surgical admissions where the patient is screened for social determinents of health: food insecurity, housing, transportation, safety and utilites	75% Internal Benchmark: Best Performing Campus rate for FY24	90% Internal Benchmark: Monthly Rate achieve by Best Performing Campus
Rate of patients who reported they would “definitely” recommend AHS	Percentage of patients who would recommend AHS (includes rehab, acute, ambulatory, ED, outpatient surgery, dental, radiology)	78.78% 2% Improvement over FY24 Baseline	79.16% 75th Percentile for Inpatient Med Surg 50th Percentile for all other areas based on Press Ganey National Database

San Leandro Hospital FY 2025 Detailed Quality OKR and KPI Dashboard

Vision: Alameda Health System will be recognized as a world-class patient and family centered system of care that promotes wellness, eliminates disparities and optimized the health of our diverse communities.

Safe Care - Caring, Healing, Teaching All			Performance			FY25 Goals		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
Provide safe care	Eliminate Patient Harms	Total Patient Harms	5	80	83	67	54	
		CLABSI # Events/SIR	0/0	0/0	2/1.69	1/1.224	0/0.756	
		CAUTI # Events/SIR	0/0	0/0	2/1.75	1/1.199	0/0.646	
		MRSA # Events/SIR	0/0	2/5.21	2/3.41	1/2.361	0/0.793	
		C. Difficile # Events/SIR	Pending/0	4/0.84	8/1.56	5/0.985	2/0.417	
		SSI # Events/SIR	0/0	2/1.42	0/0	0/0.38	1/0.756	
		Falls with Injury/% Per 1000 Days	1/0	9/0.51	11/0.78	8/0.64	6/0.49	
		HAPI #/% per 1000 Discharges	4/15.267	56/21.13	35/9.54	31/8.59	27/7.63	
		Behavior Events with Physical Injury	0/0	7/0.6	33/1.61	20/1.48	18/1.21	
		Serious Safety Events (F or Greater)	0	2	2			
	Reduce Mortality from Sepsis	Sepsis Mortality Observed:Expected	NA	1.18	1.01		1.04	
		Bundle Compliance Sepsis Early Management	50.00%	62.16%	68.90%			
	Embed Critical Behaviors	Hand Hygiene Compliance	89.90%	94.87%	95.02%			

Fiscal Year Starts in July 1 and Ends June 30

FY25 YTD is results from July 2024 to Apr 2025

Timely, Effective, and Efficient Care			Performance			FY25 Goals		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
Promote wellbeing	Provide the right care at the right time	All Cause 30-Day Readmission Rate	8.60%	13.07%	8.80%	9.96%	11.12%	
Provide accessible care	Minimize Time Spent Waiting for our Patients	ED Boarding Time for Admitted Patients	2:55	2:58	3:07	2:20	1:30	
Equitable Care			Performance			FY25 Goals		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
Serving all: Deliver equitable care	Health-related social needs recognized and addressed	Health-related social needs assessment completed on inpatients	92.70%	92.30%	94.23%	75%	90%	
		Health-related social needs referrals placed	0.00%	NA	NA	Pending	Pending	
Patient-Centered Care			Performance			FY25 Goals		
OBJECTIVES	KEY RESULTS	Detailed KPIs	Apr 2025	FY25 YTD	FY24 Actual	Improvement	Benchmark	Accountable Leaders
	Optimize performance regarding patient experience	Likelihood to recommend Acute	69.30%	66.50%	68.92%	70.30%	77.80%	
		Likelihood to recommend ED	60.61%	58.98%	58.67%	59.84%	70.10%	
		Likelihood to recommend Amb Surg	90.91%	85.12%	76.92%	78.46%	86.00%	
		Communication with Nurses	73.04%	71.99%	73.75%	75.23%	76.41%	
		Communication with Providers	77.50%	77.79%	79.41%	81.00%	83.40%	

Fiscal Year Starts in July 1 and Ends June 30

FY25 YTD is results from July 2024 to Apr 2025

Fiscal Year 2025

OKR Metric Definitions for QPSC

Metric	Definition	GOAL	
		Improvement	Benchmark
Patient Harm	The number of potential health-care acquired patient harms Includes: CLABSI, CAUTI, MRSA BSI, C-Diff, SSI for Acute Med-Surg/Critical Care, and Patient Falls with injuries, Hospital Acquired Pressure Injuries and Behavior Events that result in Injury for all areas (practically, not inclusive of ambulatory)	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile NDNQI 50th Percentile
CLABSI # Events/ SIR	A primary bloodstream infection (that is, there is no apparent infection at another site) that develops in a patient with a central line in place . #: Number of infections that occurred SIR: Standardized Infection Ratio compares the actual number of infections to the predicted number of infections. The predicted number is risk adjusted. Results less 1 are desirable	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile
CAUTI # Events/ SIR	an infection of the urinary tract caused by a tube (urinary catheter) that has been placed to drain urine from the bladder. #: Number of infections that occurred SIR: Standardized Infection Ratio compares the actual number of infections to the predicted number of infections. The predicted number is risk adjusted. Results less 1 are desirable	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile
MRSA # Events/ SIR	Potential hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA) staph infection that is difficult to treat because of resistance to some antibiotics. #: Number of infections that occurred SIR: Standardized Infection Ratio compares the actual number of infections to the predicted number of infections. The predicted number is risk adjusted. Results less 1 are desirable	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile
C. Difficile # Events/ SIR	Potential hospital acquired infection that causes diarrhea and colitis (an inflammation of the colon). #: Number of infections that occurred SIR: Standardized Infection Ratio compares the actual number of infections to the predicted number of infections. The predicted number is risk adjusted. Results less 1 are desirable	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile
SSI # Events/ SIR	an infection that occurs after surgery in the part of the body where the surgery took place. Excludes superficial infections. Attributed to date of procedure. #: Number of infections that occurred attributed to month procedure performed SIR: Standardized Infection Ratio compares the actual number of infections to the predicted number of infections. The predicted number is risk adjusted. Results less 1 are desirable	50% gap reduction to the 50th Percentile	NHSN 2022 50th Percentile
Falls with Injury/ # % Per 1000 Days	Patient Fall reported via Midas Safety Alert. # of Events / Rate: Number of events divided by number of patient days times 1000	50% gap reduction to the 50th Percentile	NDNQI 50th Percentile
HAPI #/ % per 1000 DCs	Hospital Acquired Pressure Ulcers reported via Midas Safety Alert. # of Events / Rate: Number of events divided by number of patient discharges times 1000	10% improvement as compared to Fiscal Year 2024	20% improvement as compared to Fiscal Year 2024
Behavior Events with Physical Injury	Behavior events that resulted in physicial injury via Midas Safety Alerts # of Events/Rate: Number of events divided by number of patient days times 1000	10% improvement as compared to Fiscal Year 2024	20% improvement as compared to Fiscal Year 2024
Serious Safety Events (F or Greater)			

Fiscal Year 2025

OKR Metric Definitions for QPSC

Metric	Definition	GOAL	
		Improvement	Benchmark
Sepsis Mortality O/E Ratio	The observed to expected (O:E) sepsis mortality ratio is a comparison of the actual number of sepsis-related deaths in a hospital (observed) to the predicted number of deaths (expected). Performance is considered better than expected if the O:E ratio is less than 1, and worse than expected if the ratio is greater than 1. A lower O:E ratio indicates that more people are surviving conditions that would otherwise be fatal.	NA	1.04 National Mean per Vizient
Bundle Compliance Sepsis Early Management	A set of guidelines that hospitals use to manage patients with severe sepsis or septic shock. The guidelines focus on early recognition and intervention to save lives and limbs. This is an "all-or-nothing" measure, meaning that hospitals must adhere to all elements of the bundle to receive credit. Follows CMS/TJC SEP 1 Definition		
Hand Hygiene Compliance	Hand hygiene is a leading way to reduce the spread of pathogens in healthcare settings. It includes: Washing hands with soap and water and Using an antiseptic handrub. Hand hygiene compliance is the percentage of times that a person performs hand hygiene when an opportunity arises. It's calculated by dividing the number of hand hygiene actions performed by the total number of opportunities.		
All-cause 30 day Readmissions Rate	Percentage of inpatient acute med-surg encounters, regardless of payer type, with an unplanned readmission to any AHS facility within 30 days for any cause among encounters for acute care inpatients with a principal discharge diagnosis/procedure for a clinical classification category in the Cardiorespiratory, Cardiovascular, Medicine, Neurology, or Surgery/Gynecology cohort. *Note:* This measure approximates, but likely does not match, the value of the corresponding CMS readmission measure.	50% gap reduction to the 50th Percentile CMS Hospital Compare	50th Percentile CMS Hospital Compare
NTSV Cesarean Section Rate	he NTSV C-section rate is the percentage of live babies born to women in their first pregnancy who meet the following criteria: Born at or after 37 weeks gestation Singleton (no twins or more) In the vertex presentation (no breech or transverse positions)		
ED Boarding Time Time in ED from Decision to Admit to Inpatient Bed	Median time from Decision to Admit to departure from the emergency department for admitted patients. Decision to Admit = First Admit Disposition Admit = Time patient admitted to Inpatient Unit	2:20 Community Hospitals: 50% gap closure to pre=pandemic performance 8:30 Highland: 50% gap closure to TJC benchmark	1:30 Community Hospitals: Pre-pandemic Performance 4:00 Highland: TJC guidance for max boarding time
Rate of Inpatients screened for health-related social needs (food, housing, transportation, safety, utilities) ↑	The percentage of inpatient acute medical/surgical admissions where the patient is screened for social determinents of health: food insecurity, housing, transportation, safety and utilites	75% Internal Benchmark: Best Performing Campus rate for FY24	90% Internal Benchmark: Monthly Rate achieve by Best Performing Campus
Health-related social needs referrals placed	A "health-related social needs referral" means directing a patient to a community service or organization that can address social issues impacting their health, such as food insecurity, housing instability, lack of transportation, or financial hardship, identified through a screening process within a healthcare setting; essentially, referring a patient to support that can help address social factors that could be affecting their health outcomes.	TBD	TBD
Acute: Rate of patients who reported they would “definitely” recommend AHS	Percentage of discharged inpatients who would recommend AHS	2% improvement as compared to Fiscal Year 2024	75th Percentile per Press Ganey

Fiscal Year 2025

OKR Metric Definitions for QPSC

Metric	Definition	GOAL	
		Improvement	Benchmark
Same Day Surgery:Rate of patients who reported they would "definitely" recommend AHS	Percentage of same day surgery patients who would recommend AHS	2% improvement as compared to Fiscal Year 2024	50th Percentile per Press Ganey
Emergency: Rate of patients who reported they would "definitely" recommend AHS	Percentage of Emergency patients who would recommend AHS	2% improvement as compared to Fiscal Year 2024	50th Percentile per Press Ganey
Communication with Nurses	A domain of HCAHPS which measures patients' perceptions of how well patients feel that their nurses: explained things clearly, listened carefully, and treated the patient with courtesy and respect. Percent of surveyed Inpatient discharges where patient response was highest of the scale	2% improvement as compared to Fiscal Year 2025	50h Percentile per Press Ganey
Communication with Providers	A domain of HCAHPS which measures patients' perceptions of how well patients feel that their provider(s): explained things clearly, listened carefully, and treated the patient with courtesy and respect. Percent of surveyed Inpatient discharges where patient response was highest of the scale	2% improvement as compared to Fiscal Year 2026	Per Press Ganey Community Hospitals: 75th Percentile Highland Hospital: 90th Percentile

Agenda Item D: Post Acute Presentation

ALAMEDA HEALTH SYSTEM

Post-Acute Quality Report 7/23/25

Richard Espinoza, NHA, CAO Post-Acute Services

CMS Quality Star Rating

Pillar: Quality Care Pillar
Definition: AHS provides Safe, Timely, Effective, Efficient, Equitable and Patient-Centered care that is accessible to all
Objective: Safe place to receive exceptional and compassionate care

	Key Result	Key Performance Indicators (KPIs)
	Maintain Post Acute CMS 5 STAR Ratings	5 Stars

All AHS Post-Acute SNF/SA sites:
June 2025
5-star Overall Quality Rated

The top 10% of skilled nursing facilities in the United States receive a 5-star rating from the Centers for Medicare and Medicaid Services (CMS)

Fairmont continues with 5 stars in every CMS category

CMS Overall Quality 5 Star Rating

Care Compare Five-Star Ratings of Nursing Homes

Provider Rating Report for June 2025

Ratings for Alameda County Medical Center D/P SNF (056479) San Leandro, California			
Overall Quality	Health Inspection	Quality Measures	Staffing
★★★★★	★★★★★	★★★★★	★★★★★

Care Compare Five-Star Ratings of Nursing Homes

Provider Rating Report for June 2025

Ratings for Alameda Hospital D/P SNF (555381) Alameda, California			
Overall Quality	Health Inspection	Quality Measures	Staffing
★★★★★	★★★★★	★★★	★★★

2025-2026 Focus Metrics

July 2025 items of focus taking into consideration CMS changes in metrics and areas for improvement:

- Short Stay Medicare metrics
- Staffing hour capture for PBJ (Payroll Based Journal)
- Long stay residents whose ADL needs increased
- Long stay ability to walk worsened

CDPH/CMS Visits:

- CDPH visits: 7/1/2024-6/30/25:

  AHS: Self Reports/CDPH visits: 26

  25 no finding outcomes
  1 with a finding – POC accepted and cleared

CDPH/CMS Survey outcomes

Alameda sites: Southshore, Park Bridge, AH Sub-Acute:

- Passed CDPH/CMS Federal survey with 3 findings – state average is 16.5
- Passed Life Safety survey with 1 findings – state average is 7.5

Fairmont:

- Passed CDPH/CMS Federal survey with 5 findings – state average is 16.5
- Passed Life Safety Survey with 1 finding - state average is 7.5

AH Sub-Acute DHCS Survey:

- Passed DHCS survey with 1 finding

St. Rose:

- Passed CDPH State Title 22 survey for adding beds to license – no findings
- Passed the CDPH/CMS Federal survey on 4/9-4/10/25 with zero findings – state average is 16.5
- Passed their CDPH/CMS Life Safety survey with 3 findings – state average is 6.9 (time of survey)
- CDPH has recommended certification to CMS with a date of 4/17/25
    - Application with CMS for approval.

Newsweek Best Nursing Homes

- **Park Bridge**
- **Southshore**
- **AH Sub Acute**

- 4th time making the Newsweek America's Best Nursing Homes List

Registry Reduction PA sites

- Goal was to reduce registry use by 90% in 2025
- Surpassed goal: 96% reduction in registry use

- **Fairmont**: 100% out of registry use in 2025
- **Southshore**: 100% out of registry use in 2025
- **Park Bridge**: 96% out of registry use – goal to be 100% out by Sept 1, 2025

- **Acute Rehabilitation Unit**: Has not utilized registry in several years
- **Alameda Hospital Sub-Acute**: Has not utilized registry in several years
- **St. Rose SNF/Sub-Acute**: Does not utilize registry

Miscellaneous items

- AR days:
  1) July 2024: 70.3 days – June 2025: 66 days systemwide goal: 62 days – continued work on collections, EPIC build for refinement work of billing.
- Rehabilitation:
  1) Standardizing scheduling, authorization, registration workflow for outpatient rehabilitation services for efficiency- Implementation in progress.
  2) Enhancements for AHS post operative orthopedic and hand surgery patients, acute rehab patients outpatient care access, timely appointments, documentation, customer service for patients and physicians implemented and ongoing for exceptional outcomes
  3) Outpatient service expansion plan created.
  4) Registry reduction plan in place. Currently have 8 travelers system wide in rehab – (2 Fairmont, 5 Alameda, 1 Highland) – covering for open positions, medical leave, maternity leave, etc.
- Palliative care:
  1) Pilot at Fairmont: launch Oct 2024
  2) Chaplain & Physician 2 days per week
  3) Expansion to other AHS post-acute units pending hiring of full team (APP, social work)
  4) Population Health Approach: Palliative care consultations + quality and training partnership w/ post-acute team
  5) 50% of Fairmont residents have received palliative care consultation

Thank you

Questions?