HARRISHEALTH

AMBULATORY SURGICAL CENTER AT LBJ (ASC) GOVERNING BODY

Thursday, February 19, 2026
9:00 AM

BOARD ROOM
4800 Fournace Place, Bellaire, Texas 77401

The meeting may be viewed online at: **http://harrishealthtx.swagit.com/live**

Notice: Members of the Governing Body may participate by videoconference.

Mission

Harris Health is a public, integrated health system dedicated to improving the health of our communities by delivering high-quality, person-centered care in collaboration with community and academic partners.

AGENDA

I.	**Call to Order and Record of Attendance**	**Ms. Libby Viera-Bland**	**1 min**
II.	**Approval of the Minutes of Previous Meeting** • ASC Governing Body Meeting – November 20, 2025	**Ms. Libby Viera-Bland**	**1 min**
III.	**Executive Session**	**Ms. Libby Viera-Bland**	**15 min**
A.	Discussion Regarding Medical Staff Applicants and Privileges for the Ambulatory Surgical Center, Pursuant to Tex. Occ. Code Ann. §160.007 and Tex. Health & Safety Code Ann. §161.032 to Receive Peer Review and/or Medical Committee Report in Connection with the Evaluation of the Quality of Medical and Health Care Services, Including the Review of the ASC Peer Review Program's 2025 Annual Report and Consideration of Approval of Medical Staff Applicants and Privileges for the ASC Upon Return to Open Session ***– Dr. Scott Perry***		*(5 min)*
B.	Report by the Vice President, Deputy Compliance Officer, Regarding Compliance with Medicare, Medicaid, HIPAA and Other Federal and State Healthcare Program Requirements and a Status of Fraud and Abuse Investigations, Pursuant to Tex. Health & Safety Code Ann. §161.032, Including Possible Action Regarding this Matter Upon Return to Open Session ***– Mr. Anthony Williams***		*(5 min)*
C.	Report Regarding Quality of Medical and Healthcare, Pursuant to Tex. Health & Safety Code Ann. §161.032 and Tex. Occ. Code Ann. §160.007 to Receive Peer Review and/or Medical Committee Report in Connection with the Evaluation of the Quality of Medical and Healthcare Services, the ASC Quality Scorecard, Quality Review Committee Report and Medical Executive Committee Report, Including Possible Action Upon Return to Open Session ***– Dr. Matasha Russell, Dr. Scott Perry and Mr. Matthew Reeder***		*(5 min)*

IV.	**Reconvene**	**Ms. Libby Viera-Bland**	**2 min**
V.	**General Action Item(s)**	**Ms. Libby Viera-Bland**	**5 min**

A. General Action Item(s) Related to Quality: ASC Medical Staff

1. Consideration of Approval of Credentialing Changes for Members of the Harris Health ASC Medical Staff ***– Dr. Scott Perry***

2. Consideration of Approval of Changes to the ASC OB/GYN Privileges ***– Dr. Scott Perry***

B. General Action Item(s) Related to Policy and Procedures

1. Consideration of Approval of Amended Policies and Procedures for the ASC ***– Mr. Matthew Reeder and Dr. Scott Perry***

2. Consideration of Approval of Reviewed Policies and Procedures with No Recommended Changes for the ASC ***– Mr. Matthew Reeder and Dr. Scott Perry***

VI.	**ASC Leadership Reports**	**Ms. Libby Viera-Bland**	**5 min**

A. Report Regarding Medical Staff Operations, Clinical Operations, Statistical Analysis of Services Performed and Operational Opportunities at the ASC, Including Questions and Answers
– Dr. Scott Perry and Mr. Matthew Reeder

VII.	**Adjournment**	**Ms. Libby Viera-Bland**	**1 min**

HARRISHEALTH

HARRIS HEALTH
AMBULATORY SURGICAL CENTER AT LBJ
GOVERNING BODY MEETING MINUTES
November 20, 2025
9:00 AM

AGENDA ITEM	DISCUSSION	ACTION/RECOMMENDATIONS
I. Call to Order & Record of Attendance	The meeting was called to order at 9:14 A.M. by Ms. Libby Viera-Bland, Chair. A quorum was noted as present, and attendance was recorded. Some Board members attended in person while others participated by videoconference, in accordance with state law and the Harris Health Videoconferencing Policy. Only scheduled speakers were provided dial-in information; the public was able to view the meeting live via the Harris Health website at http://harrishealthtx.swagit.com/live.	**A copy of the attendance is appended to the archived minutes.**
II. Approval of the Minutes of the Previous Meeting	• ASC at LBJ Governing Body Meeting – August 21, 2025	**Motion No. 25.11 – 14** **Moved by Ms. Carol Paret, seconded by Ms. Libby Viera - Bland,** and **unanimously approved that the Governing Body adopt the minutes of the August 21, 2025 meeting. Motion carried.**
III. Executive Session	At 9:16 A.M., Ms. Viera – Bland announced that the ASC Governing Body would enter into Executive Session for Items A through C, as permitted by law under Tex. Occ. Code Ann. §160.007 and Tex. Health & Safety Code Ann. §161.032.	
	A. Discussion Regarding Medical Staff Applicants and Privileges for the Ambulatory Surgical Center (ASC) at LBJ, Pursuant to Tex. Occ. Code Ann. §160.007 and Tex. Health & Safety Code Ann. §161.032 to Receive Peer Review and/or Medical Committee Report in Connection with the Evaluation of the Quality of Medical and Health Care Services, Including Consideration of Approval of Medical Staff Applicants and Privileges for the ASC at LBJ Upon Return to Open Session	**No Action Taken.**
	B. Report by the Vice President, Compliance Officer, Regarding Compliance with Medicare, Medicaid, HIPAA and Other Federal and State Healthcare Program Requirements and a Status of Fraud and Abuse Investigations, Pursuant to Tex. Health & Safety Code Ann. §161.032, Including Possible Action Regarding this Matter Upon Return to Open Session	**No Action Taken.**

AGENDA ITEM	DISCUSSION	ACTION/RECOMMENDATIONS
	C. Report Regarding Quality of Medical and Healthcare, Pursuant to Tex. Occ. Code Ann. §160.007 and Tex. Health & Safety Code Ann. §161.032 to Receive Peer Review and/or Medical Committee Report in Connection with the Evaluation of the Quality of Medical and Healthcare Services, Including ASC at LBJ Quality Scorecard Report, Quality Review Committee Report and Medical Executive Committee Report, Including Possible Action Upon Return to Open Session	**No Action Taken.**
IV. Reconvene	At 9:25 A.M., Ms. Viera – Bland reconvened the meeting in open session, confirmed a quorum, and noted that no action was taken in Executive Session.	
V. General Action Item(s)		
	A. General Action Item(s) Related to Quality: ASC at LBJ Hospital Medical Staff	
	1. Approval of Credentialing Changes for Members of the Harris Health Ambulatory Surgical Center Medical Staff Dr. Scott Perry, Medical Director, ASC, presented Credentialing Changes for Members of the Harris Health Ambulatory Surgical Center Medical Staff. For November 2025, there were nine (9) initial appointments. A copy of the credentialing report is available in the permanent record.	**Motion No. 25.11 – 15** **Moved by Ms. Carol Paret, seconded by Ms. Libby Viera - Bland, and unanimously passed that the Governing Body approve item V.A.1. Motion carried.**
	2. Approval of the Harris Health Ambulatory Surgical Center Scope of Services Mr. Matthew Reeder, Administrator, ASC, presented the Harris Health Ambulatory Surgical Center Scope of Services for review. He explained that the scope of services was standard for facilities transitioned to Accreditation Association for Ambulatory Health Care (AAAHC) and is reviewed annually with the policies. A copy of the policy is available in the permanent record.	**Motion No. 25.11 – 16** **Moved by Ms. Carol Paret, seconded by Ms. Libby Viera - Bland, and unanimously passed that the Governing Body approve item V.A.2. Motion carried.**

VI. ASC at LBJ Medical Director and Administrator Reports		
	A. Report Regarding Medical Staff Operations, Clinical Operations, Statistical Analysis of Services Performed and Operational Opportunities at the ASC at LBJ Including Questions and Answers Mr. Reeder provided an update regarding medical staff operations, clinical operations, and statistical analysis of services performed at the ASC at LBJ. He reported that construction had begun in October to refresh five operating suites, including upgrading lights and facilities to standardize operations. Dr. Perry discussed the strategic expansion of ophthalmology services, noting that the ASC is optimizing for ophthalmology procedures, including cataract and potentially retina cases. He reported an increase in surgical volumes for the fiscal year, with September achieving the highest volume to date. Dr. Perry also mentioned plans to procure a second surgical microscope to support multiple simultaneous procedures. Questions regarding surgery scheduling and service availability were addressed, with Dr. Perry noting that timing and surgeon availability influence scheduling capacity.	**As Presented.**
VII. Adjournment	There being no further business and without objection from the members of the Governing Body, the meeting adjourned at 9:31 A.M.	

I certify that the foregoing are the Minutes of the Harris Health ASC at LBJ Governing Body Meeting held on November 20, 2025.

Respectfully Submitted,

Libby Viera – Bland, AICP, ASC at LBJ Governing Body Chair

Recorded by Cherry A. Joseph, MBA

HARRISHEALTH

Thursday, November 20, 2025
Harris Health Ambulatory Surgical Center (ASC) at LBJ Governing Body Attendance

GOVERNING BODY MEMBERS PRESENT	GOVERNING BODY MEMBERS ABSENT	OTHER BOARD MEMBERS PRESENT
Libby Viera-Bland *(Governing Body Chair)*		
Carol Paret		
Dr. Glorimar Medina		
Matthew Reeder		
Philip Sun		
Dr. Scott Perry		

HARRIS HEALTH EXECUTIVE LEADERSHIP, STAFF & SPECIAL INVITED GUESTS	
Cherry Joseph	John Matcek
Daniel Smith	Louis Smith
Ebon Swofford *(Harris County Attorney's Office)*	Maria Cowles
Enrique Valdez	Dr. Matasha Russell
Dr. Esmaeil Porsa (*President & CEO, Harris Health)*	Micah Rodriguez
Dr. Jackie Brock	Sara Thomas *(Harris County Attorney's Office)*
Dr. Jennifer Small	Shawn DeCosta
Jennifer Zarate	Dr. Thomas Cummins
Jerald Summers	Vivian Ho-Nguyen
Jessey Thomas	

Virtual Attendee Notice: *If you joined as a group and would like to be counted as present, please submit an email to: BoardofTrustees@harrishealth.org before close of business the day of the meeting.*

BOARD OF TRUSTEES

HARRISHEALTH

Ambulatory Surgical Center at LBJ Governing Body

Thursday, February 19, 2026

Executive Session

Discussion Regarding Medical Staff Applicants and Privileges for the Ambulatory Surgical Center, Pursuant to Tex. Occ. Code Ann. §160.007 and Tex. Health & Safety Code Ann. §161.032 to Receive Peer Review and/or Medical Committee Report in Connection with the Evaluation of the Quality of Medical and Health Care Services, Including the Review of the ASC Peer Review Program's 2025 Annual Report and Consideration of Approval of Medical Staff Applicants and Privileges for the ASC Upon Return to Open Session.

- Pages 8 – 20 Were Intentionally Left Blank -

BOARD OF TRUSTEES

Ambulatory Surgical Center at LBJ Governing Body

HARRISHEALTH

Thursday, February 19, 2026

Executive Session

Report Regarding Quality of Medical and Healthcare, Pursuant to Tex. Health & Safety Code Ann. §161.032 and Tex. Occ. Code Ann. §160.007 to Receive Peer Review and/or Medical Committee Report in Connection with the Evaluation of the Quality of Medical and Healthcare Services, the ASC Quality Scorecard, Quality Review Committee Report and Medical Executive Committee Report, Including Possible Action Upon Return to Open Session.

- Pages 22 – 41 Were Intentionally Left Blank -

BOARD OF TRUSTEES

Ambulatory Surgical Center at LBJ Governing Body

HARRISHEALTH

Thursday, February 19, 2026

Consideration of Approval of Credentialing Changes for Members of the Harris Health Ambulatory Surgical Center Medical Staff

---

The ASC Medical Executive Committee and Dr. Scott Perry, MEC Chair, reviewed the attached credentialing changes for the members of the Ambulatory Surgical Center. The report is being sent for approval.

Ambulatory Surgical Center Governing Body

HARRISHEALTH

February 2026 Medical Staff Credentials Report

Medical Staff Initial Appointments: 1

Medical Staff Reappointments: 0

Medical Staff Changes in Clinical Privileges: 1

Medical Staff Resignations: 0

Other Business

Medical Staff Leave of Absence - 1

Medical Staff Files For Discussion: 0

BOARD OF TRUSTEES

Ambulatory Surgical Center at LBJ Governing Body

HARRISHEALTH

Thursday, February 19, 2026

Consideration of Approval of Changes to the ASC OB/GYN Privileges

---

A request was made to revise the ASC OB/GYN Privileges to include Female Pelvic Medicine and Reconstructive Surgery (Urogynecology) Privileges.

The Medical Executive Committee has approved the revisions to the ASC OB/GYN Privileges and requests the approval of the ASC Governing Body.

QUALIFICATIONS FOR FEMALE PELVIC MEDICINE AND RECONSTRUCTIVE SURGERY (UROGYNECOLOGY)

To be eligible to apply for core privileges in female pelvic medicine and reconstructive surgery, the initial applicant must meet the following criteria:

Meet criteria for obstetrics and gynecology, plus an American Board of Obstetrics and Gynecology (ABOG)-approved fellowship in female pelvic medicine and reconstructive surgery/urogynecology.

AND/OR

Specialty Board Certified by the AOA, an ABMS affiliated Specialty Board or one of the affiliated Boards of the Royal College of Physicians and Surgeons of Canada.

AND

Required Previous Experience: Applicants for initial appointment must be able to demonstrate performance of at least five (5) female pelvic medicine and reconstructive surgical procedures, reflective of the scope of privileges requested, in the past 12-months, or demonstrate successful completion of an ACGME- or AOA- accredited residency, clinical fellowship, or research in a clinical setting within the past 12-months.

Renewal of Privileges: To be eligible to renew core privileges in female pelvic medicine and reconstructive surgery, the applicant must meet the following maintenance of privilege criteria:
Current demonstrated competence and an adequate volume of experience five (5) procedures with acceptable results, reflective of the scope of privileges requested, for the past 24-months based on results of ongoing performance data review (OPDR) and outcomes. Evidence of current ability to perform privileges requested is required of all applicants for renewal of privileges.

Privilege Requested	Please check the privilege(s) requested	MEC Chair Approval Date
Collagen, Botox, and Periurethral injections		
Cystoscopy		
Cystotomy/cystotomy		
Multichannel urodynamic testing		
Paravaginal repair		
Perform history and physical exam		
Pubovaginal urethral suspension/sling		
Sacrocolpopexy		
Scarospinous ligament suspension		
Uterosacral culposuspension		

Thursday, February 19, 2026

Consideration of Approval of Amended Policies and Procedures for the Ambulatory Surgical Center

---

As part of the regulatory requirements of the Ambulatory Surgical Center, the Governing Body is to review and approve policies for the ACS annually.

Listed below is a summary of the policy changes, along with the attached back-up material.

- Policy ASC-P-1002: Change in context
- Policy ASC-P-1003: Change in context
- Policy ASC-P-1004: Minor change in context
- Policy ASC-P-1005: Modifications to match AAAHC
- Policy ASC-P-1008: Minor change in context
- Policy ASC-P-2016: Modifications to match system policy
- Policy ASC-P-3004: Modifications to match system policy
- Policy ASC-P-3005: Modifications to match system policy
- Policy ASC-P-4014: Modifications to match system processes and current practice standards
- Policy ASC-P-4015: Change in context and flow
- Policy ASC-P-5003: Update SRE Links
- Policy ASC-P-6003: Minor change (addition of the word "designee")
- Policy ASC-P-6005: Minor change (addition of the word "designee")
- Policy ASC-P-6008: Change in Context

**Most policies reflect updated references.*

TITLE: DISPOSAL OF OUTDATED MEDICATION

PURPOSE: To establish guidelines for the proper disposal of outdated or discontinued medications.

POLICY STATEMENT:

The Ambulatory Surgical Center (ASC) at LBJ will regularly monitor the ASC's stock of drugs and medications to ensure that all drugs ~~and medications~~ that are expired, recalled, mislabeled or deteriorated are removed from the ASC's stock of medications.

I. DEFINITIONS:

A. AUTOMATED DISPENSING CABINET (ADC): An automated medication supply system (i.e. Pyxis Med Station or Anesthesia Station) used for storage and record-keeping of medications located outside of the pharmacy department.

B. BEYOND USE DATE (BUD): The date or time after which administration of a compounded sterile product (CSP) or an opened multi-dose vial/container shall not be initiated. The BUD is determined from the date or time the preparation is opened or compounded, its chemical stability, and the sterility limits. Both the stability of the components and the sterility limits are taken into consideration when determining BUDs, and the BUD must be the shorter of the sterility dating or chemical stability dating for CSPs. The BUD is usually shorter than the manufacturer's expiration date which is the date assigned pursuant to manufacturer testing.

C. ACTION ALERT: An alert that is emailed by the Department of Pharmacy which requires several actions (e.g., reviewing medication stock, sequestering stock that is affected, reporting affected quantity, etc.).

D. DRUG (MEDICATION): Any prescription medications, sample medications, herbal remedies, vitamins, nutraceuticals (i.e., dietary supplements), vaccines, or over-the counter drugs; diagnostic and contrast agents used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions; radioactive medications, respiratory therapy treatments, parenteral nutrition, blood derivatives, and intravenous solutions (plain, with electrolytes and/or drugs); and any product designated by the Food and Drug Administration (FDA) as a drug.

Formatted: Indent: Left: 1", No bullets or numbering

Formatted: No bullets or numbering

Formatted: No bullets or numbering

E. MARKET WITHDRAWAL: Occurs when a product has a minor violation that would not be subject to the FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.

F. NOTIFICATION ALERT: An alert which does not require any action by the receiver of the notification alert unless the receiver encounters a recalled/market withdrawal product either when retrieving or administering medication. If receiver encounters a recalled/market withdrawal product, they are to sequester and contact pharmacy for immediate pick up of the product

G. RECALL: Actions taken by a manufacturer or distributor to remove a product from the market. Recalls may be conducted on the manufacturer or distributor's own initiative, by FDA request, or by FDA order under statutory authority. The following classifications may be assigned by the Food and Drug Administration (FDA):

1. Class I – A situation in which there is a reasonable probability that the use of, or exposure to, the recalled product will cause adverse health consequences or death.
2. Class II – A situation in which the use of, or exposure to, the recalled product may cause temporary or medically reversible adverse health consequences or in which the probability of serious adverse health consequences is remote.
3. Class III – A situation in which use of, or exposure to, the recalled product is not likely to cause adverse health consequences.
4. Unclassified – A situation in which a manufacturer-initiated recall has not been assigned a classification by the FDA. This may be a voluntary withdrawal or recall.

H. RECALL TRACKER: An audit tool to ensure that pharmacy complies with posted recalls.

~~I.~~II. ~~MONTHLY CHECKS FOR~~ OUTDATED MEDICATION:

A. The ASC Pharmacist-In-Charge or ~~his or her~~ designee will perform ~~monthly~~ routine inspections~~checks~~ on all medication areas~~the ASC's stock of medications~~ for the following:

1. Medication area cleanliness,
~~1.~~2. Medication~~s that are~~ expiration/beyond use date~~sed~~;
~~2.~~3. Medications that have visible deterioration; and
~~3.~~4. Medications that are improperly labeled.

Formatted: Indent: Left: 1", No bullets or numbering

Formatted: Font: Bold

B. The ASC Pharmacist-In-Charge or ~~his or her~~ designee will record in a Disposed Drug Log all medications that are found to be expired, visibly deteriorating, or improperly labeled.

~~II.~~III. DISPOSAL OF OUTDATED, MISLABELED, OR DETERIORATED MEDICATION:

A. Medications that have expired, are improperly labeled, or have visibly deteriorated will be returned to the ASC Pharmacy for disposal.

B. Medication vials/syringes that are outdated, visibly deteriorating, or mislabeled shall be discarded in an appropriate ASC approved pharmaceutical waste management container or returned to the ASC Pharmacy.

C. All expired, deteriorated, and improperly labeled medications will be properly disposed of by the ASC Pharmacy in a manner that prevents diversion or accidental ingestion.

D. If the expired, deteriorated, or improperly labeled medication is a controlled substance, an ASC Pharmacist will properly dispose of the substance in the presence of a registered nurse as a witness, and the pharmacist and nurse will document the disposal.

~~E. Recalled medication shall be returned to the ASC Pharmacy for disposal as per the manufacturer's instruction.~~

IV. DRUG RECALL NOTIFICATION AND RESPONSIBILITIES:

A. The Department of Pharmacy shall follow procedures in Appendix A of this policy to generate and email (in emergent cases, other modes of communication including text, phone may be used) the following alerts immediately upon receiving a drug recall/market withdrawal:

1. An **action alert** for Department of Pharmacy staff;

2. An **action alert** for nursing in ambulatory locations (e.g., primary care clinics, same day clinics, etc.) and Supply Chain where review and sequestering of affected stock is the responsibility of nursing and Supply Chain; and

3. A **notification alert** for Medical Staff and Nursing Staff

B. The Department of Pharmacy Inventory Manager or Designee is responsible for overseeing the management of the drug recall/market withdrawal procedure

C. Pharmacy is responsible for removing, sequestering and disposal of affected products from all Pharmacy dispensing areas, including automated dispensing cabinets, and kits containing medications.

D. Department of Pharmacy Formulary Management and Operations team shall coordinate the identification and notification of patients for drug recalls/market withdrawals that require patient notification (follow Appendix A of this policy).

E. All action alerts shall be responded to (i.e., all affected products removed, sequestered, and documented in recall tracker) within 24 business hours from receipt of action alert regardless of whether any affected product was found.

Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Heading 1, Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.25" + Tab after: 0.75" + Indent at: 0.75"
Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font: 12 pt
Formatted: Indent: Left: 1", No bullets or numbering
Formatted: Font: 14 pt
Formatted: Font: 14 pt
Formatted: No bullets or numbering
Formatted: Font: 14 pt
Formatted: Outline numbered + Level: 2 + Numbering Style: A, B, C, … + Start at: 1 + Alignment: Left + Aligned at: 0.5" + Tab after: 1" + Indent at: 1"
Formatted: Left, Indent: Left: 0", First line: 0"

REFERENCES/BIBLIOGRAPHY:

Accreditation Association of Ambulatory Health Care

42 Code of Federal Regulations (C.F.R.) §416.44(c) Building Safety

42 Code of Federal Regulations (C.F.R.) §416.48(a) Administration of drugs

APPENDICES:

Appendix	Title
A	Drug Recall/Market Withdrawal Procedure

OFFICE OF PRIMARY RESPONSIBILITY:

The Ambulatory Surgical Center (ASC) at LBJ

APPENDIX A DRUG RECALL/MARKET WITHDRAWAL PROCEDURE

Receiving Notification

The Pharmacy Inventory Manager and/or Designee determines pharmacy inventory individuals responsible for receiving recalls and market withdrawal from

- Manufacturer;
- Distributor;
- Vendor;
- Alert notification software system (Economic Cycle Research Institute (ECRI)); and
- Pharmacy area leadership team (for in-house compounded preparations) so those individuals can post to the recall tracker and email alerts.

Pharmacy Inventory Staff

1. Upon receipt of notification, the pharmacy inventory individual shall immediately review and initiate appropriate action as mandated by the recall, market withdrawal or discontinuation notification or by established internal processes should the notification not specify.

Formatted: Font: 14 pt
Formatted: Left
Formatted: Font: Not Bold
Formatted: Font: Not Bold

2. Verify purchase history.
3. Post recall or market withdrawal in Recall Tracker located in Pharmacy SharePoint.
4. Email the following:
    - An action alert for Department of Pharmacy staff;
    - An action alert for nursing in ambulatory locations (e.g., primary care clinics, same day clinics, etc.) and Supply Chain where review and sequestering of affected stock is the responsibility of nursing and Supply Chain; and
    - A notification alert for Medical Staff and Nursing staff.

Drug Recall Response (Documentation)

Each pharmacy and clinic area (nursing) shall have designated staff to respond (document in recall tracker on Pharmacy SharePoint site) to the recall within 24 business hours from receipt of alert.

Patient Notification (if required)

Pharmacy Formulary Coordinator and/or Designee

1. Coordinates with the designated P&T subcommittee to develop a communication (telephone or letter) action plan (i.e., replacement and disposal of the product in question, if necessary);
2. Coordinates with Pharmacy Operations team to submit a ticket to IT to obtain list of patients;
3. If telephone – Pharmacy Operations shall be responsible for ensuring patients are contacted and informed of P&T communication action plan
4. If letter - sends letter draft to Patient Education and Corporate Compliance for review and approval;
5. Submits final draft to letter vendor for letter vendor to mail to patients.

In-House Compounded Preparations

1. Notify Pharmacy Inventory Manager and designees so they can add to recall tracker and send action and notification alerts;
2. Notify each patient (in writing) to whom the preparation was dispensed (i.e., given to patient for administration at home)

Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold
Formatted: Font: Not Bold

3. Notify the TSBP (in writing in the form of a memo sent via email) no later than 24 hours after the recall is issued Memo shall be sent to Corporate Compliance for review and approval prior to sending to TSBP
4. Keeps written record of the recall including actions taken to notify all parties and steps taken to ensure corrective measures

All records shall be kept in the comments section within the recall tracker entry.

Product Removal

1. The existing inventory of the product in the Pharmacy shall be checked (within 24 business hours of receipt of alert) by Pharmacy personnel and shall be removed from the shelves and any automated storage or dispensing systems, if warranted, and isolated in the pharmacy.
2. Run Epic reports to determine if any recalled product has been used in in-house compounding. If so, check all compounded product, remove affected product and dispose of affected product in the black pharmaceutical waste bin.
3. Inventory Management personnel shall take measures to ensure that all future shipments of drugs are checked to be sure that no quantities of the suspected products are subsequently received in Pharmacy and/or used.

Disposal of Recalled/Market Withdrawal Products

1. All recalled/market withdrawal product shall be sent to the reverse drug distributor for proper credit and disposal with exception of compounded products involving a recall or market withdrawal product.
2. When deemed necessary, recalled products shall be returned to the appropriate manufacturer directly for proper credit, disposal and/or replacement as defined in the policy.
3. Pharmacy shall maintain documentation of all recalls/market withdrawals sent to the reverse

Formatted: Font: Not Bold

Formatted: Font: Not Bold

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.25" + Indent at: 0.5"

REVIEW/REVISION HISTORY:

Effective Date	Version # (If Applicable)	Review/ Revision Date (Indicate Reviewed or	Approved by:

		Revised)	
8/5/16	1.0	8/5/16	The Ambulatory Surgical Center (ASC) Governing Body
		Reviewed / Approved 3/29/18	The Ambulatory Surgical Center (ASC) Governing Body
		Reviewed / Approved 02/14/2019	The Ambulatory Surgical Center (ASC) Governing Body
		Approved 02/13/2020	The Ambulatory Surgical Center (ASC) Governing Body
		Reviewed / Approved 02/25/2021	The Ambulatory Surgical Center (ASC) Governing Body
		Reviewed / Approved 02/17/2022	The Ambulatory Surgical Center (ASC) Governing Body
		Reviewed / Approved 02/16/2023	The Ambulatory Surgical Center (ASC) Governing Body
		Reviewed / Approved 02/22/2024	The Ambulatory Surgical Center (ASC) Governing Body
		Reviewed / Approved 02/20/2025	The Ambulatory Surgical Center (ASC) Governing Body

TITLE: MEDICATION ADMINISTRATION

PURPOSE: To establish guidelines for the safe and accurate administration of medications to patients at the Ambulatory Surgical Center (ASC) at LBJ.

POLICY STATEMENT:

It is the policy of the Ambulatory Surgical Center (ASC) at LBJ, through the implementation of the measures outlined below, to ensure the accuracy of medication administration and the safety of patients.

POLICY ELABORATIONS:

DEFINITIONS:

A. **ADMINISTRATION SYSTEMS**: Commercial products for the preparation of IV products within a single, closed system prior to administration to a patient (i.e., 'Adapt-a-vial' and 'Add-a-vial').

B. **AUTOMATED DISPENSING CABINET (ADC)**: Advanced point of use system that automates distribution, management, and control of medications (e.g. Pyxis Med Station or Anesthesia Station). ~~An automated medication supply system (e.g., Pyxis Med Station or Anesthesia Station) used for storage and record keeping of medication.~~

C. **COMPOUNDED STERILE PREPARATION (CSP)**: A dose of a medication or nutrient prescribed for a specific patient that must be prepared for administration in a sterile environment. CSP involves specific calculation of doses and multiple transfers of product outside of original containers. "Ready to Use" commercial products, commercial administration systems, and preparation of a single medication for administration via IV push shall not be considered a CSP.

D. **ELECTRONIC MEDICATION ADMINISTRATION RECORD (EMAR)**: A point-of-care process utilizing barcode reading technology to monitor and document beside medication administration.

E. **INTRAVENOUS (IV) PUSH**: The delivery of a small volume of medication directly into the venous circulation via syringe.

F. **MEDICATION ADMINISTRATION RECORD (MAR)**: The printed and/or paper version of the eMAR.

G. **QUALIFIED LICENSED PERSONNEL (QLP)**: Any individual permitted by law and by the ASC to provide care and services, without relevant direction or supervision within the scope of the individual's license and consistent with individually granted clinical privileges.

H. **READY TO USE PREPARATION**: Pre-packaged IV mixtures prepared by a commercial vendor and ready for administration to a patient.

I. **SECURITY OF MEDICATIONS**: For the purposes of this policy, security of the storage area for medications is defined as "under the constant surveillance of authorized users or secured within a locked device, cabinet, or room where only authorized personnel have access."

J. **STANDARD CONCENTRATION**: The accepted "normal" amount of medication to be added to a specific volume of solution.

K. **WORKSTATION ON WHEELS (WOW):** A mobile station, which provides a computer, keyboard, mouse, barcode scanner, locking drawers, and monitor in order to facilitate medication administration. This unit is not designed or intended for long-term secure storage of medications. (See Appendix A)

GENERAL PROCEDURES:

L. *Orders for Medication:*

1. All medications and biologics given to patients of the ASC must be approved by a physician with a signed order.
2. Physician orders given verbally for drugs and biologics must be followed by a written order signed by the prescribing physician.

    a) The registered nurse or QLP that receives a verbal order from a physician must repeat the order back to the prescribing physician and the prescribing physician must verify that the order is correct.

b) When administering a medication pursuant to a verbal order, it must be documented in the patient's medical record that the medication was administered pursuant to a verbal order and must document the name of the prescribing physician.

3. All medication orders shall be either electronically prescribed or written on a Harris Health approved order form or approved prescription blank using a ballpoint pen. Prescriber shall only prescribe orders once the patient has been identified

~~0. Only a physician, registered nurse, or other QLP may administer the medication to the patient.~~

~~N.~~M. *Disposal of Medication:*

Medications from containers with illegible labels or drugs that have changed color, consistency or are outdated shall be returned to the ASC Pharmacy for disposal in accordance with the ASC's policy on the *Disposal of Outdated Medication*.

~~O.~~N. *Medications in the ADC:*

1. All medications and biologicals must be current, dated, and refrigerated when necessary. All medication refrigerators will be monitored for proper temperature.
2. The "override" function of the ADC shall be used to access doses when the benefit to the patient receiving the medication is greater than the risk of the pharmacist not reviewing the order prior to administration (i.e., sudden and severe change in the clinical status of the patient).

~~P.~~O. *Medication Administration:*

1. All medications administered shall have a medication order entered by a prescriber in the patient's electronic medical record.

~~1.~~2. Medications shall be administered utilizing the "eight right" of medication administration.

~~The "eight right" of medication administration includes the following:~~

a) Right drug;
b) Right dose;

c) Right route;
d) Right time;
e) Right patient;
f) Right reason;
g) Right documentation; and
h) Right assessment for administration and response to medication.

3. A Registered Nurse (RN), Prescriber, or other QLP may administer medications within their scope of practice.

~~2.~~4. Medications administrated contrary to any of the first eight "rights" shall be documented exactly as administered to the patient and entered into the Harris Health Electronic Incident Reporting System.

~~3.~~5. Medications not given, refused, or given off schedule shall be documented in the MAR.

~~4.~~6. No medication shall be left at a patient's bedside unless written by a physician.

~~5.~~7. Patients of the ASC are not allowed to self-administer medications.

~~Q.~~P. *Medication Labeling:*

1. All medications and biologicals not immediately administered and removed from the original container or packaging are labeled in a standard format in accordance with law, regulation, and standards of practice.
2. The Label must include:
   a) Medication/biological name;
   b) Medication/biological strength;
   c) Amount or volume if not apparent from the container or packaging;
   d) Expiration date a time; and
   e) The name or initials of the person transferring the drug.

~~R.~~Q. *Medication transport:*

1. WOWs may be used to securely transport medications removed from ADC to the patient's bedside for an upcoming administration. Medications shall be placed in WOW drawer and then drawer shall be locked. Storage of medications in the WOWs for purposes other than transporting from ADC to the patient's bedside is prohibited.

PROCEDURE FOR MEDICATION ADMINISTRATION:

~~S.~~R. Physicians, registered nurses, or other QLPs, shall administer medication according to the following procedure:

1. *Operating Room:*

   a) The surgeon prepares a written order prior to surgery of the medications that he or she needs for surgery.
   b) A registered nurse obtains the medication from the ADC and/or pharmacy and administers the medication to the patient pursuant to the surgeon's written order.

2. *Pre-Op:*

   a) Written Orders: The surgeon or anesthesiologist writes an order prior to admission to the ASC. A registered nurse or QLP obtains the medication from the ADC and administers the medication to the patient.
   b) Verbal Orders: The surgeon or anesthesiologist gives a verbal order to a registered nurse or QLP for a medication. The registered nurse or QLP verifies the verbal order by repeating it back and verified to the physician or surgeon. After verification of the verbal order, the registered nurse or QLP obtains the medication from the ADC and administers the medication to the patient. The Registered Nurse or QLP receiving the verbal order documents the order in the patient's medical record.

3. *Post Anesthesia Recovery Unit:*

   The Anesthesiologist provides written orders for any medications administered in the Post Anesthesia Recovery Unit.

STANDARD ADMINISTRATION TIMES:

~~T.~~S. Medication administration times are followed in accordance with the standards set forth by the Association of Perioperative Registered Nurses (AORN).

~~U.~~T. Standard administration times are followed to provide consistency for medication administration schedules with consideration of pharmacological characteristics of certain medications, and patient convenience unless otherwise noted by the physician entering the order in the patient's medical record.

MEDICATION STANDARD CONCENTRATIONS:

~~V.~~U. The ASC Pharmacy does not dispense IV CSP medications.

~~W.~~V. For medication orders with non-standard concentrations, the ASC pharmacy will contact the physician prior to the surgery in order to clarify the order and recommend an appropriate standard concentration.

~~X.~~W. The ASC pharmacy will use ready to use preparations from commercial vendors.

Appendix A: WORKSTATION ON WHEELS (WOW)

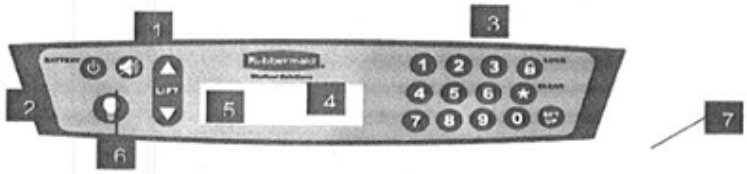
I. General Guidelines

1. One drawer per patient is designated in the WOW
2. Each cart shall have standard access codes. Unit designated codes are provided for WOWs
3. Medications are withdrawn from the Automated Dispensing Cabinet (ADC) per standard Medication Administration times and should not exceed one hour either side of administration time.
4. The person administering the medications shall assure that the time of administration is correct in the date/time field.
5. When not in use, the WOW shall be connected to an electrical outlet.
6. At the end of the shift, the nurse shall monitor to assure that his/her patients' medication drawers in the WOW are empty.
7. Prior to obtaining medications for administration to patients, the nurse checks the eMAR for any new medication orders for each assigned patient and reviews and acknowledges, when appropriate, each new order individually. There shall be no "group acknowledgement" or orders.

II. Procedure

8. Loading the WOW:
    a) Bring the WOW to the ADC area;
    b) Withdraw from ADC patient medications for the next administration period and
    c) Each patient's medications shall be placed into the WOW in an individually labeled drawer.

Rubbermaid Medical Solutions
Quick Reference Guide – AC Medication Carts



1) Height Adjustment: Press either up or down buttons to raise/lower the cart. Range is from 29" (seated) to 44" (tall/standing). Lift mechanism will stop when you release button.

2) Keyboard Light: Press this button to turn on the keyboard light for use in dark rooms. Keyboard light will turn off automatically in 1 minute – your IT staff can adjust this timing if required.

3) PIN Code Access: Enter Code to open the medication drawers. Press "Lock" to relock the drawers. Drawers will automatically lock in 2 minutes if you forget.

4) Battery Indicator: Spiral power cord should be plugged in frequently to charge the cart battery. If this indicator has only 1 or 2 bars, cart should be plugged in IMMEDIATELY. Allowing the cart power level to run all the way down can damage the cart and the cart's battery.

5) Drawer Ajar Indicator: If cart is locked, and one or more drawers are not pushed in all the way, the cart will indicate graphically which drawers are open. Push in open drawers to secure the cart.

6) Mute Button: If the cart battery drains to only 20% remaining, the cart will beep. This beeping will stop when the cart is plugged in, or when the MUTE button is hit. Note that this beeping will occur again at 10% charge, and will repeat every minute, even if the MUTE button is pressed. Cart will shut down at 7-8% power remaining, and will need to be plugged in to regain operation.

7) Keyboard Tray Lock: Red-capped lever under work surface locks the keyboard tray in place for moving between patient rooms. NOTE: Lift keyboard tray at front lip to push/pull easily.

Emergency Stop: The red emergency stop button is used to cut power to the cart's lift mechanism, in case the lift does not stop when you release the up or down button. If the lift is not working, check to be sure the E-stop button is in the "up" position.

Drawer Access Override: In case of PIN code failure, your IT staff has an override key that can be used at the back of the cart to manually operate medication drawers.

REFERENCES/BIBLIOGRAPHY:

42 Code of Federal Regulations (C.F.R.) §416.48(a).

OFFICE OF PRIMARY RESPONSIBILITY:

The Ambulatory Surgical Center (ASC) at LBJ

REVIEW/REVISION HISTORY:

Effective Date	Version # (If Applicable)	Review/ Revision Date (Indicate Reviewed or Revised)	Approved by:
9/16/16	1.0	9/16/16	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed/ Approved 3/29/18	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Approved 02/14/2019	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/13/2020	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/25/2021	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Revised / Approved 02/17/2022	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Revised / Approved 02/16/2023	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/22/2024	The Ambulatory Surgical Center (ASC) Governing Body
		Revised / Approved 08/22/2023	The Ambulatory Surgical Center (ASC) Governing Body
		Revised / Approved 08/22/2024	The Ambulatory Surgical Center (ASC) Governing Body
		Revised / Approved 02/20/2025	The Ambulatory Surgical Center (ASC) Governing Body

TITLE: POST-SURGICAL ASSESSMENTS, ANESTHESIA RECOVERY ASSESSMENTS, AND DISCHARGE REQUIREMENTS

PURPOSE: To establish guidelines that must be followed when evaluating a patient's recovery from surgery and anesthesia, and to set forth the requirements that must be met before the Ambulatory Surgical Center (ASC) at LBJ may discharge a patient.

POLICY STATEMENT:

It is the policy of the Ambulatory Surgical Center (ASC) at LBJ to assess all patients after surgery and prior to patients being discharge from the ASC.

POLICY ELABORATIONS:

I. DEFINITIONS:

RESPONSIBLE INDIVIDUAL: Someone who accompanies a patient home after a procedure or anesthesia. A legal adult who is willing and able to assist the patient in his or her immediate post-surgical recovery, including but not limited to, assisting the patient with transportation.

II. POST-SURGICAL ASSESSMENTS:

A. The overall condition of each patient of the ASC will be assessed by a physician, after each patient's surgery has been completed.

1. The patient will be assessed to determine how the patient's recovery is proceeding;
2. The patient will be assessed to determine if any steps need to be taken to facilitate the patient's recovery; and
3. The patient will be assessed to determine if the patient meets the ASC's established discharge criteria, set forth below.

B. Prior to being discharged from the ASC, patients are required to meet the following criteria:

1. Vital signs are consistent with the patient's age and pre-procedural levels;
2. Shallow cough and gag reflex present;

3. The patient is able to ambulate with minimal assistance;
4. The patient can swallow and retain some fluids;
5. There are no signs of respiratory distress;
6. Oxygen saturation is at pre-surgery level;
7. The patient is alert and oriented, or at the same mental level as the patient was prior to the surgery;
8. The patient's pain score is addressed and reasonable for the type of surgery conducted; and
9. There is minimal surgical bleeding.

C. Each patient's post-surgical assessment must be documented in the patient's medical record. Additionally, all identified post-surgical needs must be addressed in the discharge notes in the patient's medical record.

III. ANESTHESIA RECOVERY ASSESSMENTS:

A. Patients' recovery from anesthesia will be evaluated in a post-anesthesia assessment after surgery to determine whether the patient is recovering appropriately.

B. The post-anesthesia assessment must be completed by an anesthesiologist.

C. The post-anesthesia assessment must include, at minimum, an evaluation of the following criteria:

1. Respiratory function, including respiratory rate, airway patency, and oxygen saturation;
2. Cardiovascular function, including pulse rate and blood pressure;
3. Mental status;
4. Pain;
5. Nausea and vomiting; and
6. Postoperative hydration.

D. The anesthesiologist or CRNA that accompanies the patient to the PACU will provide a verbal report regarding the patient's post-surgery status to a member of the PACU team responsible for the patient. In addition, information regarding the patient's pre-operative condition and the patient's surgery must be provided to the PACU team.

E. A member of the anesthesia recovery team must remain in the post-anesthesia recovery area until the anesthesia care nurse accepts responsibility for the patient.

F. The results of the post-anesthesia assessment based on the above listed criteria must be documented in the patient's medical record. Additionally, the patient's time of arrival in the post-anesthesia recovery unit must be documented in the patient's medical record.

G. The anesthesiologist ~~A physician~~ must be in the ASC or in the Harris Health Outpatient Clinic until each patient is discharged from the post anesthesia recovery area.

IV. DISCHARGE REQUIREMENTS:

A. No patient may be discharged from the ASC without the following:

1. A post-surgical assessment;
2. A post-anesthesia recovery assessment;
3. A signed discharge order by the surgeon who performed the surgery;
4. Supplies, such as gauze, bandages, etc., sufficient to meet the patient's needs for the first night after the patient's surgery;
5. Written discharge instructions. These instructions must be given to the ~~adult responsible~~ responsible individual for the patient's care;
6. Prescriptions the patient needs to fill associated with the patient's recovery from surgery;
7. Written instructions specifying the actions the patient should take immediately after surgery to promote the patient's recovery from surgery. The instructions must be given to the ~~adult responsible~~ responsible individual for the patient's care;
8. Information regarding warning signs of complications; and
9. Information regarding how to contact the physician who will provide follow-up care to the patient.

B. Post-surgical needs must be addressed and included in the discharge notes.

C. The ASC must ensure prior to discharge that the patient is accompanied by a responsible ~~-~~individual who will provide suitable transportation for the patient and transport the patient from the ASC. The responsible individual must be willing to stay with the patient for at least twelve (12) to twenty-four (24) hours after the patient is discharged depending on the patient's procedure.

REFERENCES/BIBLIOGRAPHY:

42 Code of Federal Regulations (C.F.R.) §416.52(b) Standard: Post-surgical assessment

42 Code of Federal Regulations (C.F.R.) §416.42(a)(2) Standard: Anesthetic risk and evaluation

AAAHC Version 4~~3~~4

OFFICE OF PRIMARY RESPONSIBILITY:

The Ambulatory Surgical Center (ASC) at LBJ

REVIEW/REVISION HISTORY:

Effective Date	Version # (If Applicable)	Review/ Revision Date (Indicate Reviewed or Revised)	Approved by:
06/14/2016	1.0	06/14/2016	The Ambulatory Surgical Center (ASC) Governing Body
		Reviewed / Approved 03/29/2016	The Ambulatory Surgical Center (ASC) Governing Body
		Reviewed / Approved 02/14/19	The Ambulatory Surgical Center (ASC) Governing Body
		Approved 02/13/2020	The Ambulatory Surgical Center (ASC) Governing Body
		Reviewed / Approved 02/25/2021	The Ambulatory Surgical Center (ASC) Governing Body
		Reviewed / Approved 02/17/2022	The Ambulatory Surgical Center (ASC) Governing Body
		Reviewed / Approved 02/16/2023	The Ambulatory Surgical Center (ASC) Governing Body
		Reviewed / Approved 02/22/2024	The Ambulatory Surgical Center (ASC) Governing Body
		Revised / Approved 02/20/2025	The Ambulatory Surgical Center (ASC) Governing Body

TITLE: PRE-SURGICAL ASSESSMENTS

PURPOSE: To outline the pre-surgical assessments and exams that must be completed prior to a patient's surgery.

POLICY STATEMENT:

It is the policy of the Ambulatory Surgical Center (ASC) at LBJ to assess patients prior to surgery to determine if it is acceptable for the patient to have surgery in the ASC and to ensure positive surgical outcomes.

POLICY ELABORATIONS:

I. DEFINITIONS:

A. **PHYSICIAN**: The following individuals are physicians:

1. Doctor of medicine or osteopathy;
2. Doctor of dental surgery or of dental medicine;
3. Doctor of podiatric medicine; or
4. Doctor of optometry.

B. **QUALIFIED LICENSED PRACTITIONER**: An individual permitted by law and by the ASC to provide care and services without relevant direction or supervision within the scope of the individual's license and consistent with individually granted clinical privileges.

II. ~~COMPREHENSIVE~~ MEDICAL HISTORY AND PHYSICAL:

A. Not more than thirty (30) calendar days before the date of a patient's scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician.

B. The results of the comprehensive medical history and physical exam must be documented in the patient's medical record. Specifically, the following must be included in the patient's medical record:

1. ~~Physician name;~~
2. Patient age;

3. Pertinent past medical history (personal and family);
4. The number and type of procedure scheduled to be performed on the same date;
5. Reason and indications for procedure (chief complaint);
6. Previous significant surgeries, complications, and medical illnesses (i.e., known comorbidities);
7. Planned anesthesia level
8. Drug and biological sensitivities and allergies;
9. ~~Mental status;~~
10. Physical examination ~~including a cardio-pulmonary exam and abdominal exam;~~
11. Pre-procedure diagnosis;
Date of visit;
12. Current medications; ~~Current diagnosis~~; and

C. If a patient is scheduled for two surgeries in the ASC within a short period of time, the same comprehensive medical history and physical exam may be used if it is completed within thirty (30) calendar days before each surgery.

D. The patient's medical history and physical examination (if any) must be placed in the patient's medical record prior to the surgical procedure.

E. The comprehensive medical history and physical exam may be performed on the same day as the patient's scheduled procedure in the ASC as long as it is performed by a physician or other qualified licensed practitioner and as long as it is documented in the patient's medical record.

It is not permitted to complete the comprehensive medical history and physical exam after the patient has been prepped and brought into the operating or procedure room.

Additionally, if the comprehensive physical assessment is performed in the ASC on the same day as the surgical procedure, the assessment of the patient's procedure/anesthesia risk must be conducted separately from the history and physical, including any update assessment incorporated into that history and physical.

III. CURRENT HISTORY AND PHYSICAL:

Formatted: Font: 14 pt

Formatted: Indent: Left: 1", Hanging: 0.5", Numbered + Level: 2 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.75" + Indent at: 1"

A. Within two weeks prior to surgery, the patient's surgeon, anesthesiologist, or referring physician will assess the patient's history and perform a physical exam.

B. The H&P must indicate that the patient is cleared for surgery in an ambulatory setting.

C. The physical exam and history should cover the organs and systems commensurate with the patient's scheduled surgery.

IV. PRE-SURGICAL ASSESSMENT:

A. Upon the patient's admission to the ASC for surgery, a physician or other qualified licensed practitioner will examine the patient for any changes in the patient's condition since the completion of the current history and physical. If no changes were noted during assessment, the qualified licensed practitioner must indicate that the H&P was reviewed, and that "no change" has occurred in the patient's condition since the H&P was completed.

B. The patient must be assessed for changes in his or her condition that might be significant for the planned surgery. The assessment must identify and document any allergies the patient has to drugs and biologicals.

C. Each patient upon admission to the ASC must have a pre-surgical assessment to document at a minimum any changes in the patient's condition since the completion of the H&P.

D. If a patient H&P is conducted prior to the date of the surgical procedure, then the pre-surgical assessment must entail a separate examination in the ASC on the date of surgery. If the patient H&P is conducted after admission to the ASC and on the date of the surgery, some elements of the pre-surgical assessment may be incorporated into the H&P.

E. The patient must be assessed for Deep Vein Thrombosis~~embolism~~ (DVT) risk as part of their preadmission process.

a. The risk assessment is documented in the patient medical record; and
b. Appropriate intervention(s) will be ordered.

F. A female patient of child-bearing age may be screened with a pregnancy test. A discussion will take place between the physician and/or other qualified licensed practitioner regarding pregnancy testing. The occurrence of the discussion and the outcome must be documented in the patient's record.

G. Assessment(s) must be documented in the patient's medical record.

V. ANESTHETIC RISK AND EVALUATION:

A. Immediately prior to surgery, a physician must examine the patient to evaluate the risk of anesthesia and of the procedure to be performed on the patient.

B. The physician must verify that an anesthesia plan of care has been appropriately developed and documented in the patient's medical record.

1. The anesthetic plan of care must be based on:

a. A review of the patient's medical record;
b. The patient's medical history;
c. Prior anesthetic experiences;
d. Drug therapies;
e. Medical examination and assessment of any physical conditions that could affect the decision about the preoperative risk management;
f. A review of medical tests and consultations that might reflect on the administration of anesthesia;
g. A determination relative to the appropriate preoperative medications needed for the conduct of anesthesia; and
h. Providing appropriate preoperative instructions.

C. The exam must be specific to each patient and take into consideration the patient's current condition. Based on the exam and patient parameters set forth below, the physician will evaluate the risks associated with the patient's scheduled surgery and with the administration of anesthesia and determine whether it is appropriate to perform the procedure in the ASC.

VI. PATIENT PARAMETERS:

A. Generally, patients who do not fall within the patient parameters set forth below will not be permitted to have surgery in the ASC. However, an exception may be granted by the Medical Director of the ASC and the ASC Administrator for patients who do not fall within the patient parameters.

B. The following patient parameters will be followed when determining if a patient is eligible to have surgery in the ASC:

1. Surgical and elective procedures will only be performed on adult patients and pediatric patients more than ten (10) years of age and that fall within the American Society of Anesthesiologist status classifications: ASA Class I and ASA Class II. Surgical and elective procedures performed on adult patients and pediatric patients more than ten (10) years of age and who fall within the American Society of Anesthesiologist status classifications ASA III and ASA IV will only be permitted to have surgery at the ASC at the discretion of the Medical Director of the ASC.

2. Patients who have the following medical complications will not be permitted to have surgery or elective procedures performed at the ASC without prior consultation between the surgeon and anesthesiologist:

   a. Patients with a known risk of a difficult airway;
   b. Patients with an increased risk of developing malignant hyperthermia;
   c. Patients with predictably difficult IV access and who will likely require central venous access;
   d. Patients with a bleeding or clotting disorder;
   e. Patients with moderately severe to severe pulmonary insufficiency (e.g., OSA);
   f. Patients with unstable ischemic heart disease;
   g. Patients with poorly controlled congestive heart failure;
   h. Patients with uncontrolled hypertension and/or diabetes;
   i. Patients who have a significant probability of post-operative voiding problems;
   j. Patients with end stage renal disease;
   k. Patients with known infected wounds that will necessitate terminal cleaning of the OR;
   l. Patients with uncontrolled personality disorders;

m. Patients with uncontrolled seizure disorders;
n. Patients requiring higher levels of nursing care for any medical conditions;
o. Patients who have had a recent stroke;
p. Patients with spinal cord lesions at or above T6;
q. Patients who have taken diet medications within two weeks of the scheduled procedure;
r. Patients who have a history of arrhythmia not evaluated by a cardiologist; and
s. Patients with a BMI of greater than 50.

C. If a surgery or elective procedure on a particular patient is expected to exceed the time parameters established by state and federal laws and regulations, that patient is not permitted to have his or her surgery or procedure performed at the ASC.

REFERENCES/BIBLIOGRAPHY:

42 Code of Federal Regulations (C.F.R.) §416.52(a) Admission and pre-surgical assessment

42 Code of Federal Regulations (C.F.R.) §416.42(a) Anesthetic risk and evaluation

Clarifications to the Ambulatory Surgical Center (ASC) Interpretive Guidelines - Comprehensive Medical History & Physical (H&P) Assessment Ref: S&C-11-06-ASC

AAAHC V4~~13~~.

OFFICE OF PRIMARY RESPONSIBILITY:

The Ambulatory Surgical Center (ASC) at LBJ

REVIEW/REVISION HISTORY:

Effective Date	Version # (If Applicable)	Review/ Revision Date (Indicate Reviewed or Revised)	Approved by:
06/14/16	1.0	06/14/2016	The Ambulatory Surgical Center (ASC) Governing Body
		Reviewed / Approved 03/29/2018	The Ambulatory Surgical Center (ASC) Governing Body
		Approved 02/14/2019	The Ambulatory Surgical Center (ASC) Governing Body

		Reviewed / Approved 02/13/2020	The Ambulatory Surgical Center (ASC) Governing Body
		Reviewed / Approved 02/25/2021	The Ambulatory Surgical Center (ASC) Governing Body
		Revised / Approved 02/17/2022	The Ambulatory Surgical Center (ASC) Governing Body
		Reviewed / Approved 02/16/2023	The Ambulatory Surgical Center (ASC) Governing Body
		Reviewed / Approved 02/22/2024	The Ambulatory Surgical Center (ASC) Governing Body
		Revised / Approved 02/20/2025	The Ambulatory Surgical Center (ASC) Governing Body

APPENDIX A

1. A DVT risk assessment questionnaire is completed and orders placed by a physician prior to the surgery.

2. Orders are reviewed the day of surgery and implemented.

3. Verification of the patient medical record to ensure indication of a DVT risk assessment and appropriate orders have been performed by a physician will occur.

4. A sample DVT Risk Assessment is included in Appendix A.

TITLE: UNIVERSAL PROTOCOL (PREVENTING WRONG SITE, WRONG PROCEDURE, OR WRONG PERSON SURGERY)

PURPOSE: To define the process for the pre-procedure verification of the surgical/procedure site for patients undergoing surgery and/or invasive procedures performed at the Ambulatory Surgical Center (ASC) at LBJ.

POLICY STATEMENT:

The Ambulatory Surgical Center (ASC) at LBJ is committed to improving patient safety by preventing, reducing, and striving to eliminate the occurrence of wrong site/side; wrong procedure; and/or wrong person surgery.

POLICY ELABORATIONS:

This policy addresses the processes to ensure the correct practice is implemented for patient safety.

I. DEFINITIONS:

A. **HEALTHCARE WORKER**: A member of the surgical or procedure team (i.e., surgical technologist, Registered Nurse (RN), Licensed Vocational Nurse (LVN), dental assistant, radiology technician, etc.); other than those individuals identified as a "Qualified Medical Personnel."

B. **LATERALITY**: Indication on the operative side "Left," or "Right," as applicable.

C. **PRE-PROCEDURE VERIFICATION PROCESS**: An ongoing process on the day of the procedure of information gathering and verification, beginning with the decision to perform a surgery or procedure and continuing through all settings and interventions involved in the pre-procedure preparation of the patient up to and including the Time Out just before the start of the procedure.

D. **PROCEDURE OR SURGICAL SITE**: All procedures performed with any sort of anesthesia, including local or conscious sedation. All procedures that involve percutaneous puncture or incision of the skin, or insertion of an instrument or foreign material into the body, including but not limited to: percutaneous aspirations, biopsies, cardiac and vascular catheterizations, PICC lines, all central

line insertions, chest tube insertion, and endoscopies. Certain routine "minor" procedures are not within the scope of the Universal Protocol.

NOTE: Procedures that may be excluded are: radiation oncology, and performance dialysis (excluding insertion of dialysis catheters), venipuncture, peripheral intravenous (IV) placement, insertion of nasogastric tube, and Foley catheters unless they require anesthesia as described above.

E. **QUALIFIED MEDICAL PERSONNEL**: Individuals that are determined to be qualified by the Ambulatory Surgical Center (ASC) at LBJ to provide appropriate medical screening and who may be able to provide necessary stabilizing treatment in the event of an emergency. The Qualified Medical Personnel must be credentialed and must perform with the scope of their licensure as designated by the Medical Staff Rules and Regulations.

F. **SITE MARK**: Identification of the intended site of incision/procedure/treatment with the word "yes," using a marker that is sufficiently permanent to remain visible after completion of the skin prep. Other methods such as lines may be used in addition to, but not in place of, the word "yes."

G. **SURGICAL/PROCEDURE TEAM**: The healthcare provider, surgical assistant, anesthesiologist, certified registered nurse anesthetist, scrub nurse/technician, the registered nurse, and any other active participants who will be participating in the surgery or procedure at its inception.

H. **TIME OUT**: Confirmation of the correct patient using two patient identifiers, procedure, position, side, site, and availability of implants, special equipment, or other special requirements. Confirmation should be done with a completed surgical consent.

I. **VERIFICATION**: Confirmation of the correct patient, procedure, position, side (laterality), site, and availability of implants, special equipment, or special requirements.

II. PRE-PROCEDURE VERIFICATION PROCESS:

A. Verification of the correct patient, correct site, and correct procedure/surgery occurs at the following times:

1. At the time the procedure is scheduled;
2. At the time of pre-admission testing and assessment;
3. At the time of admission or entry into the ASC for a surgery or procedure;
4. Before the patient leaves the pre-procedure area;
5. Anytime the responsibility for the care of the patient is transferred to another member of the Surgical/Procedure Team, including anesthesia providers, at the time of and during the procedure or surgery; or
6. With the patient involved, awake, and aware if possible.

B. Pre-procedure verification occurs before the patient leaves the pre-operative/pre-procedure area. Verify the following with patient participation (if possible):

1. Correct patient identity using two identifiers;
2. Correct procedure;
3. Correct procedure side and site marked by surgeon;
4. Questions regarding the procedure/surgery resolved;
5. Properly completed procedural consent;
6. Anesthesia Consent;
7. VTE Prophylaxis addressed;
8. Equipment/Implant (s) are available;
9. All Surgical/Procedure Team members participated and agree on all elements of the Time Out; and
10. For pre-operative pain block anesthesia, verify with registered nurse
    a. Identity of patient using two (2) identifiers; and
    b. The type of block and laterality (as applicable).

C. When the patient is in the pre-procedural area, immediately prior to moving the patient to the surgical/procedure room, a checklist is used to review and verify that the following items are available and accurately matched to the patient:

1. Relevant documentation (for example, allergies, history and physical, nursing assessment, pre-surgical assessment and pre-anesthesia assessment);
2. Accurately completed and signed surgical/procedure consent forms;
3. Correct diagnostic and radiology test results (for example, radiology images and scans, or pathology and biopsy reports) that are properly labeled; and
4. Any required blood products, implants, devices, and/or special equipment for the procedure.

III. MARKING THE PROCEDURE/SURGERY SITE:

A. For all procedures or surgeries involving incision or percutaneous puncture or insertion, the intended site is marked. The marking takes into consideration laterality, the surface (flexor, extensor), the level (spine), or specific digit or lesion to be treated.

NOTE: For procedures that involve laterality of organs but the incision(s) or approaches may be from the mid-line or from a natural orifice, the site is still marked and the laterality noted.

B. The procedure site is initially marked before the patient is moved to the location where the procedure or surgery will be performed and with the patient involved, awake, and aware, if possible.

C. The procedure site is marked by a QMP or other provider who is qualified to perform the intended surgical or non-surgical invasive procedure. This individual will be involved directly in the procedure and will be present, at a minimum, for the key and critical portions of the procedure.

NOTE: Final confirmation and verification of the site mark takes place during the Time-Out.

D. The method of marking the site and the type of mark is unambiguous and is used consistently throughout the ASC.

E. The mark addresses the following:

1. Is made at or near the procedure/surgical site or the incision site. Other non-procedure/surgical site(s) are not marked unless necessary to some other aspect of care;
2. Includes the word "Yes," with or without a line representing the proposed incision;
3. Is made using a marker that is sufficiently permanent to remain visible after completion of the skin prep and sterile draping. Adhesive site markers are not to be used as the sole means of marking the site; and
4. Is positioned to be visible after the patient has had his or her skin prepped, is in his or her final position, and sterile draping is completed.

F. Alternative process for patients who refuse site markings:

1. If an adult patient refuses to have his/her site marked as per policy, the surgeon shall verify the correct patient, procedure, and side/site in comparison to the patient's signed consent form for the procedure, the history and physical, and diagnostic testing results prior to the initiation of the procedure.
2. If a pediatric patient refuses to have his or her site marked as per policy, the site may be marked with the permission of the parent guardian, or legally designated representative, after the patient is sedated or anesthetized. If the parent, guardian, or legally designated representative refuses to have the site marked, the surgeon shall verify the correct patient, procedure, and side/site in comparison to the patient's signed consent form for the procedure, the history and physical, and diagnostic testing results prior to the initiation of the procedure.

G. Alternative processes are outlined below for patients who cannot easily be marked:

1. The ASC will place a temporary unique arm band on the side of the procedure/surgery containing the patient's name and use a second identifier for the intended procedure/surgery and site in the following instances:

    a. For cases that it is technically or anatomically impossible or impractical to mark site (mucosal surfaces, perineum); and
    b. For interventional procedure cases for which the catheter/instrument site is not predetermined (for example, cardiac catheterization, pacemaker insertion).

2. For minimal access procedures that intend to treat a lateralized internal organ, whether percutaneous or through a natural orifice, the intended site is indicated by a mark at or near the insertion site and remains visible after completion of the skin preparation and sterile draping.
3. For teeth, the operative tooth name(s) and number are indicated on documentation or the operative tooth (teeth) is marked on the dental radiographs or dental diagram. The documentation, images, and/or diagrams are available in the procedure room before the start of the procedure.

4. Exemptions from site marking include midline, single organ procedures, as well as endoscopies without intended laterality. Site marking is also not required before procedures in which there is no predetermined site of insertion such as cardiac catherization and other interventional procedures. All other procedures are required to be marked.

IV. TIME-OUT PROCESS:

A. The Time-Out will be conducted prior to starting the procedure/surgery. In addition, a Time-Out will be conducted prior to the introduction of the anesthesia process for regional anesthesia. The Time-Out occurs immediately before starting the procedure/surgery as a final assessment that the correct patient, site, positioning, and procedure are identified, and that, as applicable, all relevant documents, related information, and necessary equipment are available.

B. Immediately prior to the start of the procedure, a Time-Out is initiated by the surgeon/proceduralist of record (Third year resident or higher) and includes interactive verbal communication among all relevant members of the Surgical/Procedure Team. Any team member is able to express concerns about the procedure/surgery verification.

C. During the Time-Out, other activities are suspended, to the extent possible without compromising patient safety, so that all relevant members of the team are focused on the active confirmation of the correct patient, procedure, site, and other critical elements.

D. When more than one procedure/surgery is being performed by separate Surgical/Procedure teams on the same patient, a Time-Out is performed to confirm each subsequent procedure/surgery before it is initiated.

E. The Time-Out addresses but not limited to the following:

1. Relevant documentation is complete, including
   a. Consent(s);
   b. History and Physical; and
   c. Pre-operative notes
2. Surgeon: Introduction then verbalize
   a. Patient name, DOB, MRN; procedure; and site/side marked by surgeon (confirm with consent);

b. Relevant images displayed
c. Concerns or anticipated critical events
d. Duration
e. Blood Loss
f. Fire Risk

3. Anesthesia: Introduction then verbalize
   a. Antibiotic name, dose, route, and time
   b. Allergies
   c. Post-op plan
   d. Concerns or anticipated critical events
4. Scrub Tech: Introduction then verbalize
   a. Instrument sterility
   b. Medications/solutions on field
5. Circulating RN: Introduction then verbalize
   a. Equipment, devices, implants available
   b. Blood status
6. Others: Introduction then verbalize
   a. Reason for being there
7. Surgeon
   a. Solicit questions and make the following statement: "If anyone has any concerns anytime during this case, I expect you to bring it to my attention immediately."
8. Correct patient identity using two identifiers;
9. Correct procedure;
10. Correct procedure side and site marked by surgeon;
11. Relevant documentation is complete, including:
    a. Consent(s);
    b. History and Physical; and
    c. Pre-operative notes.
12. All Surgical/Procedure Team members in the room participate and agree on all elements of the Time Out.

F. The registered nurse (circulator) or Healthcare Worker will document the required components of the Time Out in the patient's record. Additionally, if a modified Time Out is performed, an EIRS will be initiated.

G. Any discrepancies noted must be resolved before the procedure is initiated.

H. Anytime the responsibility for care of the patient is transferred to another Attending Physician, a new Time Out must be performed.

I. When other members of the Surgical/Procedural Team change after a Time Out has been completed, hand off should occur in accordance with Harris Health guidelines.

V. POST-PROCEDURE (DEBRIEF) PROCESS:

A. The debriefing is done verbally by the Attending surgeon or surgeon of record initiates; all members of the team will~~th~~ pause, listen, and participate:

1. Anesthesia, Surgeon of record, Circulating RN, Scrub Technician

PROCEDURE CONFIRMATION:

1. Name of procedures;
2. Wound class;
3. Correct instrument, sponge, and needle count;
4. All specimens identified & labeled and sent to appropriate lab (Verification with Attending Surgeon);
5. Verify the correct number of specimens obtained. All specimens identified and labeled and sent to appropriate lab, Verification with read-back to Attending Surgeon; and
6. Estimated blood loss and transfusions.

DEBRIEF:

1. What went well;
2. What can improve, and how can this improvement happen;
3. Equipment problems;
4. Any events that need reporting;
5. Changes to post-op plan Surgery and Anesthesia; and
6. Wristband on patient.

VI. PROCEDURE:

A. At the time the procedure/surgery is scheduled, the scheduler will verify the correct person, correct site, and correct procedure/surgery.

B. At the time of preadmission testing and assessment, the person(s) performing the testing and/or assessment will verify the correct person, correct site, and correct procedure/surgery.

C. At the time of admission or entry into the ASC for a procedure, the admitting person will verify the correct person, correct site, and correct procedure/surgery.

D. Before leaving the pre-procedure area, the registered nurse or Healthcare Worker will verify the correct patient, correct site, and correct procedure/surgery.

E. The patient will not be moved to the operating room from the pre-operative area until the attending surgeon is present in the ASC facility.

F. The registered nurse or Healthcare Worker assisting the surgeon will perform the following steps to implement the Universal Protocol:

1. On initial patient assessment, verify verbally with the patient, parent, or legally designated representative, the patient's identification, the scheduled procedure/surgery, side, and surgical procedure site.
2. Check the identified surgical/procedure site for site markings as appropriate. If the site has not been marked, contact the surgeon to come and mark the appropriate side/site "yes" with a marker unless contraindicated.
3. Repeat the above steps for each separate procedure when multiple procedures are planned.
4. If any discrepancies exist, notify the patient's surgeon for resolution.
5. Document any discrepancy and its resolution.

Formatted: Indent: Left: 1", First line: 0"

G. Just prior to the introduction of the anesthesia process for regional anesthesia, the anesthesia provider will request a Time-Out verbal confirmation of:

1. The correct patient identity;
2. The correct procedure/surgery side and site;
3. Agreement on the procedure/surgery to be done by all;

4. Questions regarding the procedure/surgery resolved; and
5. All Surgical/Procedure Team members participated.

H. Just prior to the initiation of the surgery, the Surgical/Procedure Team will conduct a Time Out, verbal confirmation of:

1. The correct patient identity;
2. The correct surgery/procedure site;
3. Agreement on surgery/procedure to be done by all;
4. Questions regarding the surgery/procedure resolved; and
5. All Surgical/Procedure Team members participated.

I. The registered nurse or Healthcare Worker assisting the surgeon in the patient care area will clearly document the completed components of the Universal Protocol (pre-procedure Verification, marking of the surgical site, and Time-Out) in the patient's medical record.

J. In the event the Time-Out is not completed in accordance with this policy, the registered nurse or Healthcare Worker assigned to the case will immediately report this to his or her immediate supervisor and document the incident in the electronic incident reporting system (eIRS).

REFERENCES/BIBLIOGRAPHY:

AAAHC Version 4~~3~~

OFFICE OF PRIMARY RESPONSIBILITY:

The Ambulatory Surgical Center (ASC) at LBJ

REVIEW/REVISION HISTORY:

Effective Date	Version # (If Applicable)	Review/ Revision Date (Indicate Reviewed or Revised)	Approved by:
6/14/16	1.0	06/14/16	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 03/29/18	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Approved 02/14/2019	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/13/2020	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Revised / Approved 02/25/2021	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Revised / Approved 02/17/2022	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Revised / Approved 02/16/2023	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/22/2024	The Ambulatory Surgical Center (ASC) at LBJ Governing Body

APPENDIX A
PERIOPERATIVE SURGICAL SAFETY GUIDE

Items in yellow required for emergent surgical procedure or non-surgical invasive procedure

Sign-in (Pre-Op)	Timeout (OR)	Debrief (OR)
Verified in Pre-op Area Before	Prior to any invasive action done on patient by surgical team. All activity stops, music silenced.	Before Surgeon of Record leaves the room
• OR circulator and pre-op RN confirm the following with record and patient.	• Scan patient's arm band upon entering the OR. • Surgeon of record (Third year resident or higher) initiates; all members of the team will **Pause, Listen, and Participate.** • New Surgeon or Procedure – Will require a new timeout • All Services of the case should be present at initial timeout.	• Anesthesia, Surgeon of Record, Circulating RN, Scrub Tech
• Identity – verified with wristband using two identifiers • Site/Side – verified and marked with H&P or Pre-op Note • Procedure – verified with H&P and Faculty Note • Consent – verified with H&P and Faculty Note • Allergies – verified with the patient and chart • VTE Prophylaxis addressed (chemical/mechanical) • Anesthesia consent complete **Verify:** • Equipment/implant available • Post-op location/plan • Are blood products available if indicated • For pre-op Block, Anesthesia verifies with pre-op RN 1. Identity of patient (using 2 identifiers) 2. Type of Block and laterality **3. Appropriate NPO status**	**SURGEON: Introduction then Verbalize** • Patient name, MRN, procedure, and site/side (CONFIRM WITH CONSENT FORM) • Relevant images displayed • Concerns or anticipated critical events • Duration • Blood loss • Fire Risk **ANESTHESIA: Introduction then Verbalize** • Antibiotic name, dose, route, & time • Allergies • Post-op plan • Concerns or anticipated critical events **SCRUB TECH: Introduction then Verbalize** • Instrument sterility • Medications/solutions on field **CIRCULATING RN: Introduction then Verbalize** • Equipment, devices, implants available • Blood product status **OTHERS: Introduction then Verbalize** • Reason for being there **SURGEON:** • Solicit questions ***"If anyone has any concerns anytime during this case, I expect you to bring it to my attention immediately."***	**Procedure Confirmation (Surgical/Procedure Team):** Is the patient awake (yes/no)? **If yes, debrief as appropriate** • Name of procedures • Wound class • Correct instrument, sponge, and needle count • All specimens identified & labeled and sent to appropriate lab - (Verification with Attending Surgeon) • Estimated blood loss and transfusions **Debrief (Surgical/Procedure Team)** • What went well • What can improve, and how can this improvement happen • Equipment problems • Any events that need reporting • Changes to post-op plan • Surgery • Anesthesia • Wristband on patient

TITLE: PRIVACY OFFICER ROLES AND RESPONSIBILITIES

PURPOSE: To define the roles and responsibilities of the Privacy Officer and the guidelines for his or her selection.

POLICY STATEMENT:

Because the Ambulatory Surgical Center (ASC) at LBJ ("ASC") is wholly owned by Harris Health Harris Health's President and Chief Executive Officer (CEO) will select a Privacy Officer to oversee the development~~,~~ and implementation~~, and management of the ASC's~~ of Harris Health's patient privacy program and compliance with state and federal laws and regulations governing patient privacy and Harris Health's patient privacy policies~~ and procedures, and to ensure that the policies and procedures are developed, implemented, and managed in accordance with applicable state and federal privacy laws and regulations~~.

POLICY ELABORATIONS:

I. DEFINITIONS:

A. **AUTHORIZATION**: A signed written document that allows use and disclosure of protected health information for purposes other than treatment, payment, or health care operations, or as otherwise required by law.

B. **DISCLOSURE**: The release, transfer, provision of, access to, or divulging in any manner protected health information outside of the ASC.

C. **INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI)**: Information that is a subset of health information, including demographic information collected from an individual, and:

1. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
2. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; and:

i. That identifies the individual; or

ii. With respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

D. MINIMUM NECESSARY: The minimum protected health information required to accomplish the intended purpose of the request, use or disclosure of protected health information when:
a. A workforce member uses protected health information for a specific job function;
b. Harris Health discloses protected health information to an outside entity; or
c. Harris Health requests protected health information from an outside entity

~~D.~~E. **NOTICE OF PRIVACY PRACTICES**: A document that describes how a patient's protected health information may be used and disclosed by the Ambulatory Surgical Center (ASC) at LBJ and describes how patients are able to access their protected health information.

~~E.~~F. **PRIVACY OFFICER**: An individual designated by Harris Health who is responsible for the development and implementation of the privacy-related functions of the Ambulatory Surgical Center (ASC) at LBJ.

~~F.~~G. **PROTECTED HEALTH INFORMATION (PHI)**: ~~Individually Identifiable Health Information~~ IIHIthat is created, received, transmitted, or maintained by the Ambulatory Surgical Center (ASC) at LBJ in any form or medium that relates to the patient's healthcare condition, provision of healthcare, or payment for the provision of healthcare as further defined in the HIPAA regulations. PHI includes, but is not limited to, the following identifiers:

1. Name;
2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and the equivalent geocodes, except for initial three digits of a zip code if, according to the currently publicly available data from the Bureau of Census:

   i. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
   ii. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over eighty-nine (89) and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Telephone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric Identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code, except permitted for re-identification purposes.

~~G.~~H. **USE**: Regarding protected health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

~~H.~~I. **WORKFORCE**: The members of the governing body of the Ambulatory Surgical Center (ASC) at LBJ, employees, medical staff, trainees, contractors, volunteers, and vendors.

II. RESPONSIBILITIES RELATED TO THE ASC'S PRIVACY POLICIES AND PROCEDURES:

The Privacy Officer or his or her designee, shall have the following responsibilities related to the ASC's privacy policies:

1. Developing, implementing, and managing the ASC's privacy policies.
2. Revising policies and procedures in a timely fashion in order to comply with changes in the state and federal privacy laws and regulations.
3. Reviewing the ASC's Notice of Privacy Practices and revising the Notice of Privacy Practices as needed to maintain compliance with state and federal privacy laws and regulations.
4. Assessing the ASC's processes and procedures to confirm compliance with state and federal privacy laws and regulations.
5. Responsible for the development, implementation and ongoing monitoring of Mminimum Nnecessary guidelines for the ASC Workforce members.

III. RESPONSIBILITIES RELATED TO VIOLATIONS OF THE ASC'S PRIVACY POLICIES AND PROCEDURES:

The Privacy Officer, or his or her designee, shall have the following responsibilities regarding violations of the ASC's privacy policies and procedures:

1. Investigating and responding to all complaints and/or allegations involving a violation of one or more of the ASC's privacy policies or involving a violation of state or federal privacy laws or regulations;
2. Proactively monitoring ASC Workforce members access into ASC's electronic medical record system to prevent and detect inappropriate access into patients' medical records.
3. Developing mitigation plans in response to violations of state and federal privacy laws and/or violations of the ASC's privacy policies.
4. Reporting violations of ~~Harris Health's~~ the ASC's patient privacy policies and procedures that result in a breach of patient privacy to the state and federal government and notifying patients of a breach of his or her privacy.

IV. RESPONSIBILITIES RELATED TO PATIENT PRIVACY RIGHTS:

The Privacy Officer, or his or her designee, shall:

1. Respond to and implement patient requests to amend the patient's medical record;

2. Respond to and implement patient requests to restrict access to or a use or disclosure of the patient's PHI;
3. Respond to patients requests to receive confidential communications regarding the patient's PHI;
4. Respond to patient requests for an accounting of disclosures;
5. Respond and coordinate patient requests to inspect and copy the patient's medical record;
6. Respond to patients requests to receive a copy of the ASC's Notice of Privacy Practices; and
7. Respond to patients requests to withdraw previously executed Authorizations or to opt out of fundraising or marketing activities of the ASC.

V. ADMINISTRATIVE RESPONSIBILITIES:

The Privacy Officer, or his or her designee, shall:

1. ~~Develop and oversee the privacy education program;~~
1. Develop, implement and oversee patient privacy risk assessment and auditing activities;
2. Develop and oversee the patient privacy education program;
3. Respond to federal, state,and local government inquiries and investigations involving the ASC's patient privacy policies, procedures, and any violations of the ASC's patient privacy policies and procedures;
4. Assist the ASC with the implementation of new or revised patient privacy policies and procedures;
5. Monitor the ASC's compliance with federal and state patient privacy laws and regulations;
6. Partner with the Harris County Attorney's Office to ensure all Business Associate Agreements and Data Use Agreements are in place where necessary and serve when needed as a consultant and/or review the terms of those agreements when necessary; and
7. Serve as a consultant and subject matter expert for all members of the Workforce on patient privacy related matters or issues

~~Respond to federal, state, and local government inquiries and investigations involving the ASC's privacy policies, procedures, and any violations of the ASC's privacy policies and procedures;~~

~~Assist the ASC with the implementation of new or revised privacy policies and procedures;~~

~~4. Monitor the ASC's compliance with federal and state privacy laws and regulations.~~

REFERENCES/BIBLIOGRAPHY:

42 C.F.R. §416.50(g).

Health Insurance Portability and Accountability Act of 1996, Pub. L. NO. 104-191, 110 Stat. 1936 (1996) (codified at 45 C.F.R. §§ 160.00, 162.00, 164.00) (1996)).

45 C.F.R. §164.508(a)(3).

45 C.F.R. §164.514(f).

45 C.F.R §164.530(a)(1).

TEX. HEALTH AND SAFETY CODE §181

OFFICE OF PRIMARY RESPONSIBILITY:

The Ambulatory Surgical Center (ASC) at LBJ

REVIEW/REVISION HISTORY:

Effective Date	Version # (If Applicable)	Review/ Revision Date (Indicate Reviewed or Revised)	Approved by:
8/5/16	1.0	Reviewed / Approved 08/05/2016	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/14/2019	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Revised/ Approved 02/13/2020	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/25/2021	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/17/2022	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Revised / Approved 02/16/2023	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/22/2024	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Revised / Approved 02/20/2025	The Ambulatory Surgical Center (ASC) at LBJ Governing Body

TITLE: INFORMATION SYSTEMS PASSWORD REQUIREMENTS

PURPOSE: To describe the requirements for creating passwords and utilizing other security features to protect against unauthorized access to the Ambulatory Surgical Center (ASC) at LBJ and Harris Health System's information systems.

POLICY STATEMENT:

Pursuant to the Letter of Agreement between Harris Health System and the Ambulatory Surgical Center (ASC) at LBJ, Harris Health will maintain access controls that require strong and unique account passwords for information systems. These access controls assist Harris Health in protecting information systems and resources from unauthorized access on behalf of the ASC.

POLICY ELABORATIONS:

I. DEFINITIONS:

A. **CHIEF INFORMATION SECURITY OFFICER (CISO)**: An individual designated by Harris Health who is responsible for the management and supervision of the use of security measures to protect data and the conduct of workforce members in relation to the protection of data.

B. **PRIVACY OFFICER**: An individual designated by Harris Health who is responsible for the development and implementation of the privacy-related functions of the ASC.

C. **SYSTEM ADMINISTRATOR**: The individual responsible for the operations of maintaining a computer system. These operations include, but are not limited to:~~The individual responsible for the operations of maintaining a computer system. These operations include, but are not limited to:~~

1. User account creation/modification/termination;
2. System backups; and/or
3. System configuration changes.

These activities may be performed independent of, or in conjunction with, Harris Health's Information Security department or Harris Health's Information Technology department.

D. **VIOLATION**: An infraction of a HIPAA or other privacy or security policy, procedure, safeguard, or law that may or may not result in damage to the ASC or Harris Health or exposure of the ASC or Harris Health to liability, fines, or penalties.

E. **WORKFORCE**: The members of the governing body of the Ambulatory Surgical Center (ASC) at LBJ, employees, medical staff, trainees, contractors, volunteers, and vendors.

II. PASSWORDS:

~~Pursuant to the Letter of Agreement between Harris Health and the ASC, Harris Health's Information Security department has developed the following password standards for the ASC:~~

1. Passwords must be changed every ~~ninety~~ (90) days; on all application and system accounts or upon suspicion or confirmation of compromise.
2. ~~Passwords may only be reused after four (4) different passwords have been previously used;~~
2. Password changes should be performed only after user identity is verified
3. Passwords may not be repeated until the fifth consecutive password change.
3.4. It is recommended to use a passphrase (see example below) instead of a password. Both passwords and passphrases must contain three of the following gour character types:~~Where possible passwords must contain three (3) of the following four (4) character types~~:

    a. Lower case alpha characters;
    b. Upper case alpha characters;
    c. Numbers; and
    d. Special characters (e.g.! $, #, %, etc.) where allowed by the system.

Passphrase example: monkey_pencil_h0use

~~4.~~5. Passwords and passphrases must have a minimum of ~~twelve~~ (12) characters.

B. After five ~~(5)~~ failed log in attempts, the system account will be locked and the Workforce member must request a reset of the account through the ~~Harris Health's~~ Self Service Password Reset tool or by calling ~~Harris Health's~~ the Information Technology Service D~~d~~esk.

C. Individuals with named user accounts shall not share passwords with anyone.

D. Passwords for named user accounts must be memorize and Workforce members should never document or record passwords with any corresponding account information or user names.

~~D.~~E. Hardcoding: Passwords for application and system accounts that can be used for interactive login are not permitted to be hardcoded in scripts, configuration files, source code, or any other file. Instead, secure methods such as environmental variables, vaults, or password managers should be used to store and manage passwords.

III. SCREEN LOCKING:

A. Workforce members who leave ~~his or her~~their computer workstation are required to manually lock ~~his or her~~their computer.

B. All computers, unless otherwise authorized, shall be configured to automatically invoke the screen saver after a period of inactivity. After five ~~(5)~~ minutes of inactivity, the screen will fade to black to shield the screen from plain view. After an additional five minutes of inactivity (~~ten~~ (10) minutes total) the screen saver will activate and will require the user to enter a password to unlock the computer. These controls ~~will~~ help protect computers from unauthorized access.

C. Screens can be locked manually by depressing the ~~Crtl~~Ctrl-Alt-Delete button and selecting "Lock T~~t~~his Computer" on the options screen.

D. All Harris Health mobile devices, unless otherwise authorized, shall be configured to automatically lock after a defined period of inactivity.

E. Mobile devices must be set to lock after five minutes of inactivity to protect sensitive data from unauthorized access.

~~C.~~F. To unlock the mobile device, users must enter their secure password, PIN, or use biometric authentication (e.g., fingerprint or face recognition).

IV. ENFORCEMENT AND EXCEPTIONS:

A. Any Workforce member found to have violated this policy may be subject to disciplinary action as outlined in the ASC Sanctions policy.

B. Requests for exceptions to the Screen Locking procedures in this policy must be submitted in writing with a business justification to Harris Health's CISO. Harris Health's CISO and Privacy Officer will evaluate the request for approval or disapproval. Request for exceptions may be submitted at informationsecurity@harrishealth.org.

REFERENCES/BIBLIOGRAPHY:

42 Code of Federal Regulations (C.F.R.) §416.50(g).

OFFICE OF PRIMARY RESPONSIBILITY:

The Ambulatory Surgical Center (ASC) at LBJ

REVIEW/REVISION HISTORY:

Effective Date	Version #	Review/ Revision Date	Approved by:

	(If Applicable)	(Indicate Reviewed or Revised)	
08/05/2016	1.0	08/05/2016	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 03/29/2018	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/14/2019	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/13/2020	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/25/2021	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/17/2022	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Revised / Approved 02/16/2023	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/22/2024	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/20/2025	The Ambulatory Surgical Center (ASC) at LBJ Governing Body

TITLE: INFORMATION SECURITY RISK ASSESSMENT

PURPOSE: To address regulatory and industry best practices and standards, an Information Security Risk Assessment program has been established to evaluate and document information security controls to appropriately mitigate risk from vendors, applications, medical devices or services to the Ambulatory Surgical Center (ASC) at LBJ

POLICY STATEMENT:

Pursuant to the Letter of Agreement between Harris Health and the Ambulatory Surgical Center (ASC) at LBJ, Harris Health will maintain an Information Security Risk Assessment program on behalf of the ASC as a security standard for all work locations. This program will require implementation of standards and procedures to prevent, detect, contain, and correct information security violations that occur within the ASC.

This policy applies to all ASC at LBJ Workforce members and Business Associates using or accessing the ASC's information or information systems.

POLICY ELABORATIONS:

I. DEFINITIONS:

A. **ACCEPTANCE OF RISK FORM:** A form generated by Information Security that must be signed by senior business stakeholders in the event that a risk related to a vendor or technology system ("System") is determined to be unacceptable by Information Security but the business still wants to implement the system or service. The form documents the business stakeholders' receipt of the Risk Assessment Decision and their acknowledgement of the risks identified therein and must be approved and signed off on by the data owner, Chief Information Officer (CIO), and Chief Risk and Compliance Officer (CRCO).

B. **ELECTRONIC PROTECTED HEALTH INFORMATION (ePHI)**: Protected health information that is created, received, maintained, or transmitted by electronic means.

C. **INFORMATION SECURITY RISK ASSESSMENT (ISRA):** The process of identifying risks to organizational operations (including mission, functions, image, reputation), and organizational assets, resulting from the operation of an

information system. This process incorporates threat and vulnerability analyses, and considers mitigations provided by security controls planned or in place.

D. **INFORMATION SYSTEM:** Any telecommunications and/or computer related equipment or interconnected system or subsystems of equipment used in the acquisition, storage, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of voice and/or data (digital or analog); including software, firmware, and hardware.

E. **INHERENT RISK:** The level of risk present with a vendor, application, or service without considering controls. This is based on a number of factors, including but not limited to, types and volumes of data, business dependency, and regulatory impacts.

F. **LEGACY SYSTEM:** An information system that is based on outdated technologies, but is critical to day-to-day operations.

G. **RISK:** A factor, event, element, or course that exposes Harris Health to liability, potential financial loss, and/or data loss.

H. **RISK ASSESSMENT DECISION FORM:** The Risk Assessment Decision Form (RAD) is used to communicate Risk Assessment decisions to the data owner and the project manager, including any required conditions for approval.

I. **RISK ASSESSMENT REPORT:** The Risk Assessment Report is used to document necessary security controls based on the information provided in the System Security Validation Document (SSVD) and other supporting documentation.

J. **SYSTEM SECURITY VALIDATION DOCUMENT (SSVD):** The SSVD is a validation document used to collect the information required to facilitate an information security risk assessment.

K. **THREAT:** Any circumstance or event with the potential to cause harm to an information system in the form of destruction, disclosure, adverse modification of data, and/or denial of service, or something or someone that can intentionally or accidentally exploit a vulnerability.

L. **VULNERABILITY**: A weakness identified with a vendor, application, or service that a potential threat actor could exploit to harm the confidentiality, availability, or integrity of Harris Health's data or affect patient safety

M. **WORKFORCE**: The members of the governing body of the Ambulatory Surgical Center (ASC) at LBJ, employees, medical staff, trainees, contractors, volunteers, and vendors.

II. ROLES AND RESPONSIBILITIES:

A. Pursuant to the Letter of Agreement between Harris Health and the ASC, Harris Health's Information Security department will oversee Risk Assessment activities related to HIPAA security on behalf of the ASC.

B. **DATA OWNER:** Has administrative control and is accountable for adhering to the conditions of approval as stated in the RAD. Additionally, has management responsibility for controlling the use and disposition of an application, record, or database resource. The data owner is, in many cases, external to Information Security or Information Technology. This role must be a Harris Health employee with a title of Director or above.

C. **CHIEF COMPLIANCE & RISK OFFICER (CCRO):** In the event that a vendor, application or service is not approved by the Chief Cyber & Information Security Officer (CCISO) after the completion of an ISRA, the CCRO may accept the risk in conjunction with the Chief Information Officer (CIO) and the highest departmental Senior Business Leader (EVP/Sr. EVP) through the Acceptance of Risk Form. The CCRO retains the ultimate responsibility for accepting the security risks identified in the ISRA.

D. **CHIEF INFORMATION OFFICER (CIO):** In the event that a vendor, application or service is not approved by the CCISO after the completion of an ISRA, the CIO may accept the risk in conjunction with the Chief Compliance Officer (CRCO) and the highest departmental Senior Business Leader (EVP/Sr. EVP) through the Acceptance of Risk Form.

E. **CHIEF CYBER & INFORMATION SECURITY OFFICER (CCISO):** The CCISO is responsible for reviewing the Risk Assessment Report and Risk

Assessment Decision Form concerning a vendor, application, or service. The CCISO acts in an advisory capacity when determining risk and does not own the security risks identified in the ISRA.

F. **INFORMATION CUSTODIAN:** The Information Custodian has technical control and is responsible for the safekeeping and maintenance of data and the management of underlying systems that retains data. The Information Custodian provides technical information and details of the system, vendor or service to the Risk Assessor/Analyst.

G. **PROJECT MANAGER:** The Project Manager is responsible for notifying Information Security of new technology solutions or system changes/upgrades being introduced to the Harris Health environment so an ISRA can begin. The Project Manager is further responsible for providing the Risk Assessor/Analyst with any information required to complete a Risk Assessment Report.

H. **RISK ASSESSOR/ANALYST:** The Risk Assessor/Analyst is responsible for facilitating the ISRA process with the project manager/data owner, evaluating the security risks posed by a vendor, application, or service, and completing the Risk Assessment Report. The Risk Assessor/Analyst will provide the Risk Assessment Report and Risk Assessment Decision Form to the CCISO for final review approval.

I. **SYSTEM ADMINISTRATOR:** The System Administrator is responsible for the maintenance and operation of computer systems. The day-to-day activities may include but are not limited to user account creation, modification, termination, system backups, and/or system configuration changes. These activities may be performed independent of, or in conjunction with, Harris Health Information Security and Information Technology.

J. **USER:** Any person who reads, enters, updates, sends, copies or prints information using any information system. Users must have an informational need to know and must be authorized by the Data Owner information owner.

III. INFORMATION SECURITY RISK ANALYSIS:

A. An enterprise-wide risk analysis will be performed by Information Security or designated third party vendor at least annually.

B. The risk analysis process identifies potential threats to, and vulnerabilities of, Harris Health information systems containing ePHI. The risks that Harris Health decides to address, and how Harris Health decides to address the risks, will depend on the probability and likely impact of threats affecting the confidentiality, integrity, and/or availability of ePHI. Threats may affect information (data) and systems.

C. Harris Health will identify, analyze, and prioritize risks to the confidentiality, integrity, and availability of ePHI held by Harris Health.

D. The identification, analysis, and prioritization of risks will be in a documented risk analysis. Usual and customary steps for performing the risk analysis include:

1. Document Harris Health's current Information Systems that create, receive, maintain or transmit ePHI, including the system's purpose, description, and criticality. Criticality is the degree of impact on the organization if the application and/or related data were unavailable for a period of time.
2. Identify potential dangers to the information systems (threats) and system weakness that could be exploited (vulnerabilities), as well as the existing controls to reduce the risk of the threat exploiting the vulnerability.
3. Identify the likelihood of threat occurrence based on an analysis of the probability that a given threat is capable of exploiting a given vulnerability.
4. Assess the severity of impact or harm that may result from a threat triggering or exploiting a given vulnerability.
5. Determine the risk level for each identified risk based on its likelihood and severity given the existing controls.
6. Identify and document appropriate security measures and safeguards to address the identified risks. Those risks with a higher risk score require more immediate attention.

~~III.~~IV. INFORMATION SECURITY RISK ASSESSMENT:

A. An ISRA must be performed before purchasing or implementing a new technology solution; applying changes in production that may impact security safeguards (e.g., upgrades, downgrades, modifications, etc.), including legacy systems or affecting production data. The ISRA must be performed regardless of the type of data to be stored, processed or transmitted

B. Before submitting a request for ISRA, t~~T~~he data owner or the assigned~~/P~~project M~~m~~anager is responsible for obtaining project approval from the Technology Governance Committee.~~initiating a risk assessment process by creating a helpdesk ticket, which will be assigned to the Information Security Risk Assessment team.~~

C. The Information Security department most annually request, review, and document identified critical vendor's most recent available SOC 2 Type II and Penetration test reports as part of the Third-Party Risk Management (TPRM). If these reports or evidence of any other required security conditions are not available, then Information Security must document the alternate measure(s) that will be taken to evaluate the risks (i.e., reassessment). Additionally, Information Security must coordinate with the critical vendor and other appropriate parties to obtain and document explicit confirmation from the vendor that Harris Health's data will be stored in the U.S.

D. Once the project has been approved by the Technology Governance Committee, the data owner/project manager is responsible for initiating a risk assessment process in ISRA by creating a helpdesk Service Desk Request, which will be assigned to the Information Security Risk Assessment team.

~~C.~~E. The Risk Assessor/Analyst will work with project managers, data owners and system administrators to conduct an information security risk assessment and document threats, vulnerabilities and impact to the confidentiality, integrity, and availability of EPHI that Harris Health creates, receives, maintains, or transmits in accordance to HIPAA requirements.

~~D.~~F. Risk Assessments are structured and performed in accordance with the relevant security controls contained in the National Institute of Standards and Technology (NIST), Health Information Trust Alliance (HITRUST), Payment Card Industry (PCI) and other Cybersecurity Framework (CSF) as deemed necessary.

~~E.~~G. The timeline to complete a Risk Assessment depends on whether all required information has been provided to the Information Security Risk Assessment team for review. Once all information has been received, it takes approximately 20 business days to complete the Risk Assessment.

~~F.~~H. The ISRA consists of determining the inherent risks associated with a vendor, application, or service that could impact the confidentiality, integrity, or availability of Harris Health infrastructure or data. Security controls of the vendor, application, or service will be considered during the ISRA process and based on the findings, a risk determination together with control recommendations will be provided to the business stakeholders (e.g., Data Owner, Project Manager).

~~G.~~I. Information Security will conduct risk re-assessments at least every two years, or as needed, to ensure that the security controls recommended during the initial risk assessment were implemented and data/infrastructure is reasonably and appropriately protected.

~~H.~~J. The Data Owner must sign off on the Risk Assessment Decision Form to acknowledge reading, understanding, and agreeing to abide by the conditions for approval listed in the Risk Assessment Decision Form (if any).

K. Information Security will conduct risk re-assessments at least every two years, or as needed, to ensure that the security controls recommended during the initial risk assessment were implemented and data/infrastructure is reasonably and appropriately protected. The re-assessments will be prioritized based on the final Risk ranking as below:

1. High Risk Applications:

   i. Applications with High-Risk ratings will be re-assessed one year after implementation or go-live date until such time that the application's risk is downgraded to at least a medium risk.

   ii. The Data Owner will provide Information Security team with evidentiary information confirming that the security conditions of approval were implemented.

   iii. Information Security will retain the provided evidentiary information in the team's shared drive for future reference.

iv. High Risk applications will be reassessed on an annual basis.

2. Medium Risk Applications:

i. Applications with Medium-Risk ratings will be re-assessed three years after implementation or go-live date and every three years thereafter.

3. Low Risk Applications:

i. Applications with Low-Risk ratings will not be re-assessed.

L.

~~I.~~M. The Acceptance of Risk Form requires sign off by the highest departmental Senior Business leader (EP/Sr. EVP), CIO, and CCRO should the business choose to implement a vendor solution, application or service against Information Security's advisory.

REFERENCES/BIBLIOGRAPHY:

42 Code of Federal Regulations (C.F.R.) §416.5(g).

Harris Health System Policy 3.11.800 Information Security

Harris Health System Policy 3.11.805 Information Security Audit

Harris Health System Policy 3.11.808 Information Security Awareness and Training Policy

OFFICE OF PRIMARY RESPONSIBILITY:

The Ambulatory Surgical Center (ASC) at LBJ

REVIEW/REVISION HISTORY:

Effective Date	Version # (If Applicable)	Review/ Revision Date (Indicate Reviewed or Revised)	Approved by:
08/05/2016	1.0	08/05/2016	The Ambulatory Surgical Center (ASC) at LBJ Governing Body

		Reviewed / Approved 03/29/2018	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/14/2019	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/13/2020	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/25/2021	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/17/2022	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/16/2023	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Revised/ Approved 02/22/2024	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Revised/ Approved 02/20/2025	The Ambulatory Surgical Center (ASC) at LBJ Governing Body

TITLE: PROFESSIONAL PRACTICE EVALUATION

PURPOSE: To establish a positive educational approach to performance issues and a culture of continuous improvement for Physicians/Practitioners and Advanced Practice Professionals (APP) which includes fairly, effectively, and efficiently evaluating the care being provided, comparing it to established patient care protocols and benchmarks when possible.

POLICY STATEMENT:

The Ambulatory Surgical Center (ASC) at LBJ Professional Practice Evaluation (PPE) includes several components. The PPE process described in this policy is used when questions or concerns are raised about a practitioner's or APP's clinical performance. This process has traditionally been referred to as "peer review." This Policy will provide constructive feedback, education, and performance improvement assistance to Practitioner's and APP's regarding the quality, appropriateness, and safety of the care they provide. This Policy will guide the ASC to disseminate lessons learned and promote education sessions to allow Practitioner's and APP's to benefit from the PPE process and participate in the culture of continuous improvement. The Policy will also promote the identification and resolution of ASC process issues that may adversely affect the quality and safely of care being provided to patients.

POLICY ELABORATIONS:

I. DEFINITIONS:

A. **Assigned Reviewer:** A Practitioner or APP who is requested by the ASC Medical Director to:

1. Serve as a consultant and assist performing the review; or
2. Conduct a review, document his/her clinical findings on a case review form, submit the form to the ASC Medical Director that assigned the review, and be available to discuss findings and answer questions.

B. **APP or Advanced Practice Professional:** Shall have the same meaning as that term is defined in the Medical Staff Bylaws

C. **Clinical Specialty Review Committee (CSRC):** A committee of at least one Practitioner or APP from the ASC, working in conjunction with the ASC Medical Director. The individual(s) and committee that will function as CSRCs will be

designated by the ASC MEC Medical Director. CSRCs receive cases for review, obtain input from assigned reviewers as needed, complete the case review form in this Policy, and make a determination as described in Section 2.D of this Policy.

D. **Executive Session:** Any meeting or portion of any meeting, of any section, department, or committee of the Medical Staff at which privileged and/or confidential information regarding quality assessment and improvement and/or peer review information is presented or discussed.

E. **Medical Executive Committee:** A multi-specialty medical peer review committee that oversees the professional practice evaluation process, conducts case reviews, works with Practitioners and APPs in a constructive and educational manner to help address clinical performance issues, and develop Voluntary Enhancement Plans as described in this Policy. The ASC MEC has the authority to conduct non-routine, formal investigations and to recommend restrictions of clinical privileges to the Governing Body. The composition and duties of the ASC MEC are described in the Medical Staff Bylaws.

F. **Peer Review:** A process used when questions or concerns are raised about a Practitioner's or APP's clinical performance.

G. **Practitioner:** Shall have the same meaning as that term is defined in the Medical Staff Bylaws.

H. **Professional Practice Evaluation:** Refers to the ASC's routine peer review process. It is used to evaluate a Practitioner's or APP's professional performance when any questions or concerns arise. The PPE process outlined in this Policy is applicable to all Practitioners and APPs and is not intended to be a precursor to any disciplinary action, but rather is designed to promote improved patient safety and quality through continuous improvement.

I. **Professional Practice Evaluation Specialist:** Refers to the clinical staff from the Clinical Performance department who support the professional practice evaluation process described in this Policy. This includes, but not limited to, gathering and summarizing information from review of the medical record, other

relevant documentation, interviews, and the practitioner's practice evaluation history.

J. **Voluntary Enhancement Plan:** A plan designed to bring about sustained improvement in an individual's practice and may include any activity that the ASC MEC determines will help the Practitioner or APP to improve, are not disciplinary in nature, and not reportable to the National Practitioner Data Bank or any state licensing board.

K. **Workforce:** The members of the governing body of the Ambulatory Surgical Center (ASC) at LBJ, employees, medical staff, trainees, contractors, volunteers, and vendors.

II. PEER REVIEW

A. The ASC at LBJ will confirm an individual's competence to exercise newly granted privileges described in the Initial and Annual Performance Review (Policy ASC-P-4018) for recently granted privileges.

1. Evaluate a Practitioner's or APP's competence on an ongoing basis is described in the Ongoing Performance Data Review Policy (Policy ASC-P-4016).

2. Concerns regarding a Practitioner's or APP's professional conduct or health status shall be reviewed in accordance with the Medical Staff Professionalism Policy (ASC-P-4015) or Practitioner and Professional Health Policy (ASC-P-4017), respectively.

3. If a matter involves both clinical and behavioral concerns, the ASC Medical Director shall coordinate the reviews. The behavioral concerns shall be addressed pursuant to the Professionalism Policy.

III. PROCESS

A. The process by which the Peer Review process occurs is illustrated in Appendix A, Flowchart of Professional Practice Evaluation Process and the ASC Medical Executive Committee (MEC) Case Review Algorithm. The ASC shall utilize adverse outcomes, clinical occurrences, or complications as described by the accrediting body that oversees the ASC as events to activate the PPE process. The

ASC MEC will review and approve the activating events to evaluate their effectiveness. Members of the ASC Workforce may report ~~to the ASC Medical Director~~ concerns related to the safety or quality of care provided to a patient by an individual Practitioner or APP to the ASC Medical Director or through some other approved Harris Health reporting mechanism (e.g. Harris Health's electronic incident reporting system (eIRS) or Compliance Hotline) . ~~The ASC PPE review form may be used for this purpose.~~ Cases or issues may be identified for review through other means, including but not limited to those described in the PPE Manual (PPE Triggers that Prompt the PPE Review Process). Individuals who report concerns will receive a follow-up communication, either verbally or in writing. A template for response, Response to Reported Concerns, is included in this Policy.

IV. PPE SPECIALIST:

A. All cases or issues identified for review shall be referred to the PPE Specialist. They will record the issue that facilitates subsequent tracking and analysis of the case or issue such as a confidential database or spreadsheet.

B. The PPE Specialists will review, as necessary, the medical record, other relevant documentation, and the Practitioner's or APP's professional practice evaluation history. The PPE Specialists may also interview and gather information from Harris Health employees, Practitioner's, APP's, patients, family, visitors, and others who may have relevant information.

C. For any specific concerns that may be referred for review from a significant safety event or sentinel event, interviews and other fact-finding events should be coordinated between the two processes, to the extent possible, to avoid redundancy and duplication of effort.

D. The PPE Specialists shall consult with the Chair of the ASC MEC if there is any uncertainty about the proper determination or review process for a case. The PPE Specialists will then:

1. Determine if no further review is required and close the case pursuant to criteria approved by the ASC MEC. The PPE Specialists may not close cases that were commenced by a reported concerns from a Practitioner or

APP. The PPE Specialists will provide periodic reports to the ASC MEC of cases closed pursuant to this subsection. Such reports should include the

specific trigger that causes the case to be identified so the ASC MEC can evaluate the utility of such triggers;

2. Send an Awareness Letter based on criteria approved by the ASC MEC or at the discretion of the ASC Medical Director; See Section ~~G~~ IX.C. of this policy; and

3. Determine that further review is required.

E. Preparation of Case for Further Review: The PPE Specialists shall prepare cases that require further review. Preparation of the case may include the following:

1. Completion of the appropriate portions of the ASC PPE case review form;

2. As needed, modifying the case review form to reflect specialty-specific issues, as may be directed by the ASC Medical Director;

3. Preparation of a timeline or summary of the care provided;

4. Identification of relevant patient care protocols or guidelines; and

5. Identification of relevant literature.

V. TRIAGE AND REF~~G~~ERRAL OF CASE FOR FURTHER REVIEW:

A. In their discretion, the ASC Medical Director may develop standard operating procedures to guide the triage and referral of cases for further review as described in this section.

B. The PPE Specialists will refer most cases requiring further review to the appropriate CSRC. The PPE Specialists will consult with the ASC MEC Medical Director if there is any uncertainty about which CSRC should review a case.

1. A case shall be referred to the ASC MEC ~~designated~~ by the ASC MEC Medical Director if the ASC MEC Medical Director determines the case involves a concern for which expedited review is needed.

2. Referrals to the ASC MEC in Executive Session:

a) If a Voluntary Enhancement Plan is currently in effect, the PPE Specialists will consult with the ASC Medical Director to determine

if the case should be referred directly to the ASC MEC rather than to a CSRC.

b) The Chief of Service, working with the ASC Medical Director, may direct the PPE Specialists to refer a case directly to the ASC MEC if they determine that the case raises unusual or significant concerns for which direct referral to the ASC MEC is the most appropriate review process.

3. Referrals Involving Certain Complex Cases:

a) Practitioner's or APP's from two or more specialties or Clinical Services;

b) A member of the CSRC who would otherwise be expected to review the case; or

c) A matter for which necessary clinical expertise is not available on the Medical Staff the PPE Specialists will consult with the ASC Medical Director regarding referral of the case. The ASC Medical Director will determine the appropriate review process, and may decide that two or more CSRCs will review the case and complete assessments simultaneously, that an assigned reviewer will complete the review, or that the case will be referred to the ASC MEC so that an external review may be obtained, see Section ~~I.A~~XI. of this Policy.

VI. CLINICAL SPECIALTY REVIEW COMMITTEE (~~CRSE~~CSRC) ~~(ASC MEDICAL EXECUTIVE COMMITTEE)~~

A. When a case is assigned to a CSRC, a member of the CSRC will conduct the initial review of the case on behalf of the CSRC and then discuss the case with the other member(s) of the CSRC in reaching a determination. The CSRC member and CSRC shall complete the case review form.

B. The CSRC member conducting the initial review or the CSRC may seek assistance from an Assigned Reviewer. The Assigned Reviewer will generally serve as a consultant to the CSRC member or CSRC. As may be requested, the Assigned

Reviewer may also complete a case review form and report his or her findings back to the CSRC member or CSRC. In all cases, the CSRC remains responsible for completing the case review form.

C. If a CSRC member or an Assigned Reviewer has any questions or concerns about the care provided by the Practitioner or APP, the CSRC member or Assigned Reviewer shall obtain input from the Practitioner or APP prior to completing the review. Section 4 of this Policy and the PPE Manual (Request for Input from Practitioner or APP sent by CSRC, AR, or ASC MEC) contain additional information on obtaining input from the Practitioner or APP.

D. CSRCs may, with the agreement of the ASC MEC Medical Director:

a) Determine that no further review is required and the case is closed;

b) Send an Educational Letter to the Practitioner or APP;

c) Conduct or facilitate Collegial Counseling with the Practitioner or APP; or

d) Report their findings to the ASC MEC for determination.

E. Input from the Practitioner or APP must be obtained before an Educational Letter is sent or Collegial Counseling is conducted. See Section XG of this policy.

VII. AMBULATORY SURGICAL CENTER MEDICAL EXECUTIVE COMMITTEE (MEC) EXECUTIVE SESSION

A. The ASC MEC will periodically review reports of cases closed and other determinations by individuals under this Policy. If the ASC MEC disagrees with a determination made by other parties, the ASC MEC may consult with the party

who made the prior determination and may conduct an additional review of the case.

B. The ASC MEC shall consider the Case Review Forms, supporting documentation, input obtained from the Practitioners or APPs involved, findings, and recommendations for all cases referred to it.

C. A member of the CSRC responsible for the initial assessment, an Assigned Reviewer, ASC Medical Director, or designee, should present the case to the ASC MEC.

D. The ASC MEC shall determine whether any additional clinical expertise is needed to adequately identify and address concerns raised in the case. If additional clinical expertise is needed, the ASC Medical Director may:

1. Invite a specialist on the ASC Medical Staff with the appropriate clinical expertise to attend an ASC MEC meeting as a guest to assist the ASC MEC in its review of issues, determinations, and follow-up actions;
2. Assign the review to a Practitioner or APP on the Medical Staff with the appropriate clinical expertise, with a report of the assessment back to the ASC MEC; or
3. Arrange for an external review from an individual not on the Medical Staff in accordance with this policy

E. If the ASC MEC has questions or concerns about the care provided by the physician or APP, the ASC MEC may obtain additional input from the physician

or APP beyond what has already been obtained, prior to making any final determinations or findings.

F. Based on its review of all information obtained, including input from the physician or APP, the ASC MEC may:

1. Determine that no further review or action is required. If information was sought from the Practitioner or APP involved, the Practitioner or APP shall be notified of the determination;
2. Send an Educational Letter. See Section ~~G~~ IX of this policy;
3. Conduct or facilitate Collegial Counseling. See Section ~~H~~IX of this policy; or
4. Develop a Voluntary Enhancement Plan, after consultation with the Medical Director. See Section ~~G~~ IX of this policy.

G. As noted in Section ~~G~~ X of this policy, input from the physician or APP must be obtained before an Educational Letter is sent, Collegial Counseling is conducted, or a Voluntary Enhancement Plan is proposed. In making this determination, the ASC MEC should consult the guidance in the Case Review Algorithm set forth in Appendix A.

VIII. ASC MEC OFFICERS:

A. Matters that require expedited review given the seriousness of the issue may be referred by the ASC MEC Medical Director to an ASC MEC Officer(s). In such case, the ASC MEC Officer(s) will conduct a preliminary review, take action necessary to protect patients, commence the process to obtain additional expertise if needed, and refer the case to a CSRC of the full ASC MEC for review.

B. Timeframes for review:

1. The time frames specified in this section are provided only as guidelines. All participants in the process shall use their best efforts to adhere to these

guidelines, with the goal of completing reviews, from initial identification to final determination, within 90 days.

2. Assigned Reviewers are expected to either consult with the CSRC member, CSRC, or ASC MEC, depending on who requested assistance, or submit a completed case review form, if applicable, within 14 calendar days of;
   a) The review being assigned; or
   b) Their receipt of any requested input from the Practitioner or APP, whichever is later.
3. The CSRC member who conducts the initial review is expected to submit the completed portion of the case review form within 14 calendar days of the following, whichever is latest:
   a) The review being assigned;
   b) Receipt of any requested input from the Practitioner or APP;
   c) Receipt of information from an Assigned Reviewer or a case review form, if applicable. The CSRC is then expected to complete its review within 30 calendar days of the following, whichever is later;
   d) Its receipt of the CSRC members assessment; or
   e) Its receipt of any additional input requested from the Practitioner or APP.
4. If an external review is sought as set forth, those involved will use their best efforts to take the steps needed to have the report returned within 30 days of the decision to seek the external review.
5. Cases may be closed according to the process set forth in this Policy if a determination is made that there are no clinical issues or concerns presented in the case that require further review. Documentation of cases that are closed shall be provided to the PPE Specialists, who shall maintain records of closed cases and provide periodic reports to the ASC MEC. If information was sought from the Practitioner or APP involved, the

Practitioner or APP shall also be notified of the determination. A letter that may be used for that purpose is included in the PPE Manual.

C. If the ASC MEC determines that a Practitioner or APP provided exemplary care in a case under review, the Practitioner or APP should be sent a letter recognizing such efforts.

D. This Policy outlines collegial and progressive steps that can be taken to address clinical concerns about a Practitioner or APP. However, a single incident or pattern of care may be of such concern that more significant action is required. Therefore, nothing in this Policy precludes an immediate referral of a matter to the ASC MEC pursuant to the Medical Staff Bylaws or the elimination of any particular step in the Policy when deemed necessary under the circumstances. Such referral shall not preclude other action under applicable policies including policies of the ASC, Baylor College of Medicine, The University of Texas Health Science Center at Houston's McGovern Medical School, or other third-parties with Practitioners or APPs on the ASC's Medical Staff.

IX. OPTIONS TO ADDRESS CLINICAL CONCERNS:

A. This Policy and the case review form in the PPE Manual discourage the use of any scoring, leveling, or grading of cases because those practices, while traditional, can foster a punitive, isolating, and destructive culture surrounding PPE activities. Instead, this Policy focuses on specific efforts to address any issues that may be identified in a constructive and educational manner and thus foster a culture of continuous improvement. As such, this Policy encourages the use of initial mentoring efforts and progressive steps by the ASC medical staff in order to successfully address questions relating to an individual's clinical practice.

B. Initial Mentoring Efforts may include, but are not limited to, discussions, mentoring, coaching, and sharing of comparative data. There is no requirement that input be obtained prior to Initial Mentoring Efforts or that they be documented. However, brief documentation is encouraged to help determine if any pattern may be developing that would recommend a more formal response. Any documentation will be maintained in the Practitioner's or APP's confidential

file. A description of Initial Mentoring Efforts and progressive steps is included in this policy.

C. For matters that are reported to, or identified by, the PPE Specialists and reviewed under this Policy, the ASC Medical Staff will generally use Progressive Steps to address performance issues that may be identified. Additional information on each of the following Progressive Steps may be found in the PPE Manual. ~~this Policy. A description of Initial Mentoring Efforts and Progressive Steps is included in this Policy.~~

1. Awareness Letters are ~~I~~intended to make Practitioners and APPs aware of an expectation or requirement. They are non-punitive, informational tools to help Practitioners and APPs self-correct and improve their performance through timely feedback.

   a) The ASC MEC will prepare a list of objective occurrences for which an Awareness Letter will be sent to a Practitioner or APP. The list may be modified by the ASC MEC at any time. An Awareness Letter can also be sent at the discretion of the ASC Medical Director.

   b) PPE Specialists will generate an Awareness Letter to be sent to a Practitioner or APP upon the occurrence of an event which has been identified ahead of time by the ASC MEC or at the discretion of the

ASC Medical Director. The Awareness Letter will be signed by the ASC ~~MEC~~Medical Director.

~~c)~~2. Educational letters ~~D~~describe the opportunities for improvement that were identified in the care reviewed and offer specific recommendations for future practice. Formatted: Heading 3

~~d)~~a) Educational Letters may be sent by a CSRC, with the agreement of the ASC MEC Medical Director.

~~e)~~b) The Medical Director will be informed of the substance of any Educational Letter and may contact the PPE Specialists to review a copy of the letter.

~~f)~~c) A Sample Educational Letter is included in this policy.

~~g)~~3. Collegial Counseling is ~~A~~a formal, planned, face-to-face discussion between the Practitioner or APP and the ASC Medical Director. Formatted: Heading 3

~~h)~~a) A CSRC, with the agreement of the ASC Medical Director may use Collegial Counseling to address concerns with a Practitioner or APP.

~~i)~~b) Collegial Counseling shall be followed by a letter that summarizes the discussion and the recommendations and expectations regarding the Practitioner's or APP's future practice at the ASC.

~~j)~~c) The ASC Medical Director shall be informed of the substance of any Collegial Counseling and the follow-up letter, regardless of who conducts or facilitates it, and may contact the PPE Specialists to review a copy of the follow-up letter.

~~k)~~d) A Collegial Counseling Checklist to help prepare for such a meeting and a Sample Follow-Up Letter to Collegial Counseling are included in this Policy.

~~D.~~4. A Voluntary Enhancement Plan may be developed by ~~T~~the ASC MEC ~~may develop a Voluntary Enhancement Plan~~ to bring about sustained improvement in an individual's practice. This Policy provides examples of the elements that may be included in a Voluntary Enhancement Plan. However, a Voluntary Enhancement Plan may include any activity that the Formatted: Heading 3

ASC MEC determines will help the Practitioner or APP to improve and is not disciplinary in nature. Additional guidance on Voluntary Enhancement Plans is included in the PPE Manual, including Voluntary Enhancement Plan Options – Implementation Issues Checklist and a Voluntary Enhancement Plan Template Letter.

~~1.~~a) If a Practitioner or APP disagrees with the need for a Voluntary Enhancement Plan developed by the ASC MEC, the Practitioner or APP is under no obligation to participate in the Voluntary Enhancement Plan. In such case, the ASC MEC cannot compel the Practitioner or APP to agree with the Voluntary Enhancement Plan. Instead, the ASC MEC may take other appropriate action pursuant to the Medical Staff Bylaws to resolve the matter.

~~2.~~5. Awareness Letters, Educational Letters, follow-up letters to Collegial Counseling, and Voluntary Enhancement Plan documentation will be placed in the Practitioner's or APP's confidential file and considered in the reappointment process.

~~3.~~6. All Initial Mentoring Efforts and Progressive Steps are part of the ASC's confidential performance improvement and PPE/Peer Review activities. Information related to them will be maintained in a confidential manner consistent with their privileged status under state and federal law.

X. OBTAINING INPUT FROM THE PRACTITIONER

A. Obtaining input from the Practitioner or APP under review is an essential element of a transparent and constructive review process. Accordingly, no Educational Letter, Collegial Counseling, or Voluntary Enhancement Plan shall be implemented until the Practitioner or APP is first notified of the specific concerns and provides input as described in this Section. Prior notice and a request for input are not required before an Awareness Letter is sent to a Practitioner or APP.

B. The Practitioner or APP shall provide input through a written description and explanation of the care provided, responding to any specific questions posed in the correspondence to the Practitioner or APP (e.g., email or letter). Upon the request of either the Practitioner or APP, or the person or committee conducting

the review, the Practitioner or APP may also provide input by meeting with appropriate individuals to discuss the issues.

C. As part of a request for input pursuant to this Policy, the person or committee requesting input may ask the Practitioner or APP to provide a copy of, or access to, medical records from the Practitioner's or APP's office that are relevant to a review being conducted under this Policy. Failure to provide such copies or access will be viewed as a failure to provide requested input.

D. Since this policy does not involve disciplinary action or restrictions of privileges, the specific identity of any individual reporting a concern or otherwise providing information about a matter (the "reporter") will not be disclosed to the Practitioner or APP unless the individual consents or the information is later used to support an adverse professional review action that results in a Medical Staff hearing.

E. Retaliation Prohibited: Retaliation by the Practitioner or APP against anyone who is believed to have reported a concern or otherwise provided information about a matter is inappropriate conduct and will be addressed through this Policy.

F. Individual members of the ASC MEC should not engage in separate discussions with a Practitioner or APP regarding the review of a case unless the committee in question has asked the individual committee member to speak with the Practitioner or APP on its behalf. Similarly, unless formally requested to do so, Practitioners or APPs may not provide verbal input to the PPE Specialists or to any other individual and ask that individual to relay that verbal input to an individual or MEC involved in the review. The goal of these requirements is to ensure that all individuals and committees involved in the review process receive the same, accurate information. Practitioners and APP's must also refrain from any discussions or lobbying with other Medical Staff members or Governing Body members outside the authorized review process outlined in this Policy.

G. A Practitioner or APP is required to provide written input or attend a meeting as requested by a CSRC and/or the ASC MEC within the time frame specified by

the committee. Failure to respond within the specified timeframe may mean the review will proceed without input from the Practitioner or APP.

XI. ADDITIONAL PROVISIONS GOVERNING THE CLINICAL REVIEW PROCESS

A. Obtaining an external review is within the discretion of the ASC MEC acting in consultation with Harris Health's Chief Medical Executive. No Practitioner or APP has the right to demand the ASC obtain an external review in any particular circumstance.

1. If a decision is made to obtain an external review, the Practitioner or APP involved shall be notified of that decision and the nature of the external review. Upon completion of the external review, the Practitioner or APP shall be provided a copy of the reviewer's report (except that any comments related to care provided by other individuals shall be redacted).

2. The report of the external reviewer is a record of the committee that requested it and will be maintained in a confidential manner as described in this Policy.

B. Quality of care and patient safety depend on many factors in addition to Practitioner or APP performance. If system processes or procedures that may have adversely affected, or could adversely affect, outcomes or patient safety are identified through the process outlined in this Policy, the issue shall be referred to the ASC MEC. The referral will stay on the ASC MEC's agenda until it determines the issue has been resolved.

C. Peer learning sessions and the dissemination of educational information through other mechanisms are integral parts of the PPE/peer review process and assist Practitioners and APPs in continuously improving the quality and safety of the care they provide. These activities will be conducted in a confidential manner, consistent with their confidential and privileged status under the state peer review

protection law and any other applicable federal or state law. Additional guidance on peer learning sessions is included in the PPE Manual.

D. Maintaining confidentiality is a fundamental and essential element of an effective professional practice evaluation process.

1. All documentation that is prepared in accordance with this Policy shall be managed in a manner reasonably calculated to assure privacy and shall be maintained in appropriate Medical Staff files. All documents (whether paper or electronic) should be conspicuously marked with the notation "Confidential PPE/Peer Review" or words to that effect, consistent with their privileged and protected status under state or federal law. However, failure to mark documents in this manner shall not be viewed as an indication that the document is not privileged.

2. Telephone and in-person conversations should take place in private, at appropriate times, and locations to minimize the risk of a breach of confidentiality.

3. Secure institutional e-mail may be used to communicate between individuals participating in the professional practice evaluation process, including with those reviewing a case and with the Practitioner or APP whose care is being reviewed. Communication should include a standard convention, such as "Confidential PPE/Peer Review Communication" in the subject line. Communication via e-mail should not be sent to personal e-mail accounts unless;

   a) The e-mail merely directs recipients to check their secure institutional e-mail; or

   b) The email is encrypted in a manner.

4. Information that is generated pursuant to this PPE Policy may not be documented in risk management files or disclosed as part of any risk management activities.

5. All individuals involved in the PPE process, Medical Staff and ASC members, will maintain the confidentiality of the process. All such

individuals should sign an appropriate Confidentiality Agreement. Any breaches of confidentiality by Practitioners or APPs will be reviewed under the Medical Staff Professionalism Policy. Breaches of confidentiality by ASC employees will be referred to human resources.

6. The Practitioner or APP under review must also maintain information related to the review in a strictly confidential manner, as required by Texas law. The Practitioner or APP may not disclose information to, or discuss it with, anyone outside of the review process set forth in this Policy without first obtaining the permission of the ASC MEC Medical Director, except for any legal counsel who may be advising the Practitioner or APP. Violations of this provision will be reviewed under the Medical Staff Professionalism Policy.

~~7.~~E. Before any correspondence, that includes a deadline for a response, is conveyed to a Practitioner or APP, a reasonable attempt at verbal communication, e.g. a phone call, should be made to alert the Practitioner or APP that the correspondence is being sent. The intent of any such communication is to make the Practitioner or APP aware of the correspondence so that the deadline is not missed. However, failure to send communication shall not be cause for the Practitioner or APP to miss a deadline.

~~8.~~F. Except as noted below, a physician who has a supervisory or collaborative relationship with an APP for state licensure purposes shall be kept apprised of any concerns that are reviewed pursuant to this Policy involving the APP. Without limiting the foregoing, the supervising or collaborating physician will be copied on all correspondence that an APP is sent under this Policy and may be invited to participate in any meetings or interventions. The supervising or collaborating physician shall maintain in a confidential manner all information related to reviews under this Policy and may be required to sign a Confidentiality Agreement. Notification to the supervising or collaborating physician as described in this Section is not required, or may be delayed, if the individual or committee

conducting the review determines that notification would be inconsistent with a fair and effective review.

~~F.~~G. The ASC MEC is responsible for the PPE/quality assurance process described in this Policy, subject to the oversight of the Governing Body. To promote a prompt and effective review process, the ASC MEC may delegate to the PPE Specialist(s), Assigned Reviewers, and/or CSRC members, the authority to perform the functions described in this Policy on behalf of the ASC MEC. Actions taken by these individuals will be reported to and reviewed by the ASC MEC as set forth in this Policy.

1. When a function under this Policy is to be carried out by one of the individuals identified in the prior subsection, by a member of ASC, or by an ASC Medical Staff member, the individual, or the committee through its chair, may delegate performance of the function to a qualified designee who is a Practitioner, APP, or ASC employee (or a committee of such individuals). Any such designee must treat and maintain all information in a strictly confidential manner and is bound by all other terms, conditions, and requirements of this Policy. In addition, the delegating individual or committee is responsible for ensuring that the designee appropriately performs the function in question. Any documentation created by the designee are records of the committee that is ultimately responsible for the review in a particular matter.

2. When an individual assigned a function under this Policy is unavailable or unable to perform that function, one or more ASC Medical Staff members may perform the function personally or delegate it to another appropriate individual as set forth above.

~~F.~~H. To promote the collegial and educational objectives of this Policy, all discussions and meetings with a Practitioner or APP shall generally involve only the Practitioner or APP and the appropriate Medical Staff members and ASC personnel. No counsel representing the Practitioner, APP, Medical Staff, or the ASC shall attend any of these meetings. At their discretion, ASC Medical Staff leaders may permit a Practitioner or APP to invite another Practitioner or APP to the meeting. In such case, the invited Practitioner or APP may not participate in

the discussion or in any way serve as an advocate for the Practitioner or APP under review, must sign a Confidentiality Agreement, and may be required to leave the meeting at any time.

Practitioners or APPs may not create an audio or video recording of a meeting nor may they broadcast it in any manner. If a recording is made in violation of this rule, the recording shall be destroyed. In their discretion, Medical Staff may require that smart phones, tablets, and/or similar devices be left outside the meeting room. In exceptional circumstances, ASC Medical Staff or personnel may record a meeting if necessary to prepare accurate minutes or an interview summary. Once the document is prepared, however, any such recording shall also be destroyed.

XII. PROFESSIONAL PRACTICE EVALUATION REPORTS

A. A Practitioner or APP history report showing all cases that have been reviewed for a Practitioner or APP within the past three years and their dispositions should be generated for each Practitioner or APP for consideration and evaluation by the appropriate ASC Medical Director and the ASC MEC in the reappointment process.

B. The PPE Specialist(s) shall prepare reports at least annually that provide aggregate information regarding the PPE process. These reports shall be disseminated to the ASC MEC, Practitioners and APP's at the ASC, and the Governing Body for the purposes of reinforcing the primary objectives outlined in Section 1. A of this policy and permitting appropriate oversight.

C. The PPE Specialists shall prepare reports as requested by the ASC Medical Director, ASC MEC, or the Governing Body.

XIII. PPE MANUAL

The ASC MEC shall recommend Governing Body approval of forms, template letters, and other documents that assist with the implementation of this Policy. Collectively, these documents are known as the Professional Practice Evaluation Manual. Such documents shall be developed and maintained by the PPE Specialists. Individuals performing pursuant to this Policy should use the

document currently approved for that function and revise per the current ASC processes.

XIV. SUBSTANTIAL COMPLIANCE:

While every effort will be made to comply with all provisions of this Policy, substantial compliance is required. Technical or minor deviations from the procedures set forth within this Policy do not invalidate any review or action taken.

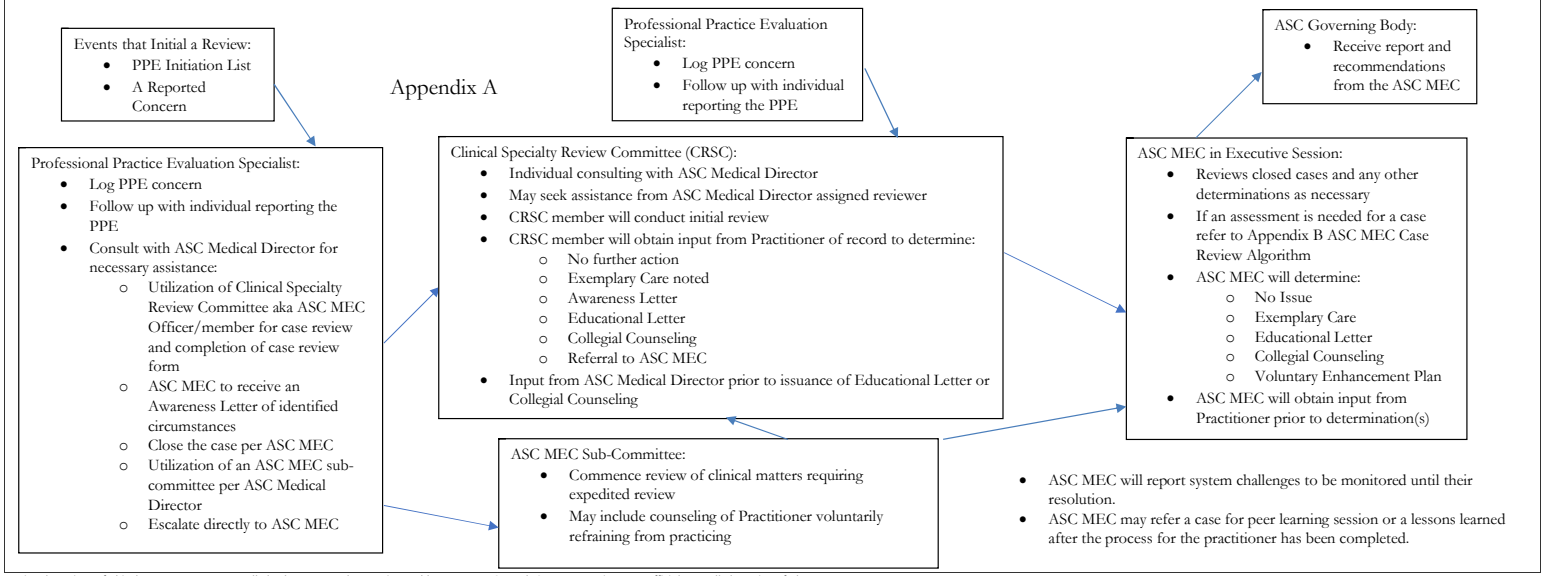
XV. AGREEMENT TO VOLUNTARILY REFRAIN FROM EXERCISING CLINICAL PRIVILEGES OR OTHER PRACTICE CONDITIONS:

A. At any point in the review process described in this Policy, the ASC MEC or a representative designated by the ASC MEC Medical Director may ask a Practitioner or APP to voluntarily refrain from exercising clinical privileges while the review proceeds. As an alternative, ASC Medical Staff leaders and the Practitioner or APP may also agree upon practice conditions that will protect the Practitioner, APP, patients, and staff during the review process. Prior to any such action, the Practitioner or APP shall be given the opportunity to discuss these issues with the ASC MEC Medical Director or their representatives and provide written input regarding them.

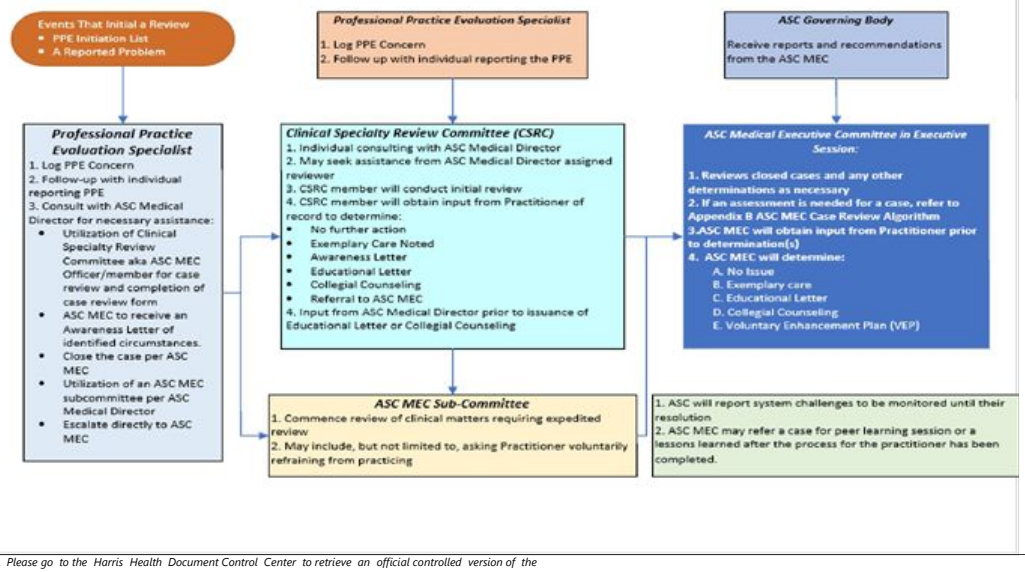
B. These actions are not considered to be disciplinary actions and do not imply any admission by the Practitioner or APP or final finding of responsibility for the concerns that have been raised. They are temporary precautions and reflect professionalism and cooperation with the review process.

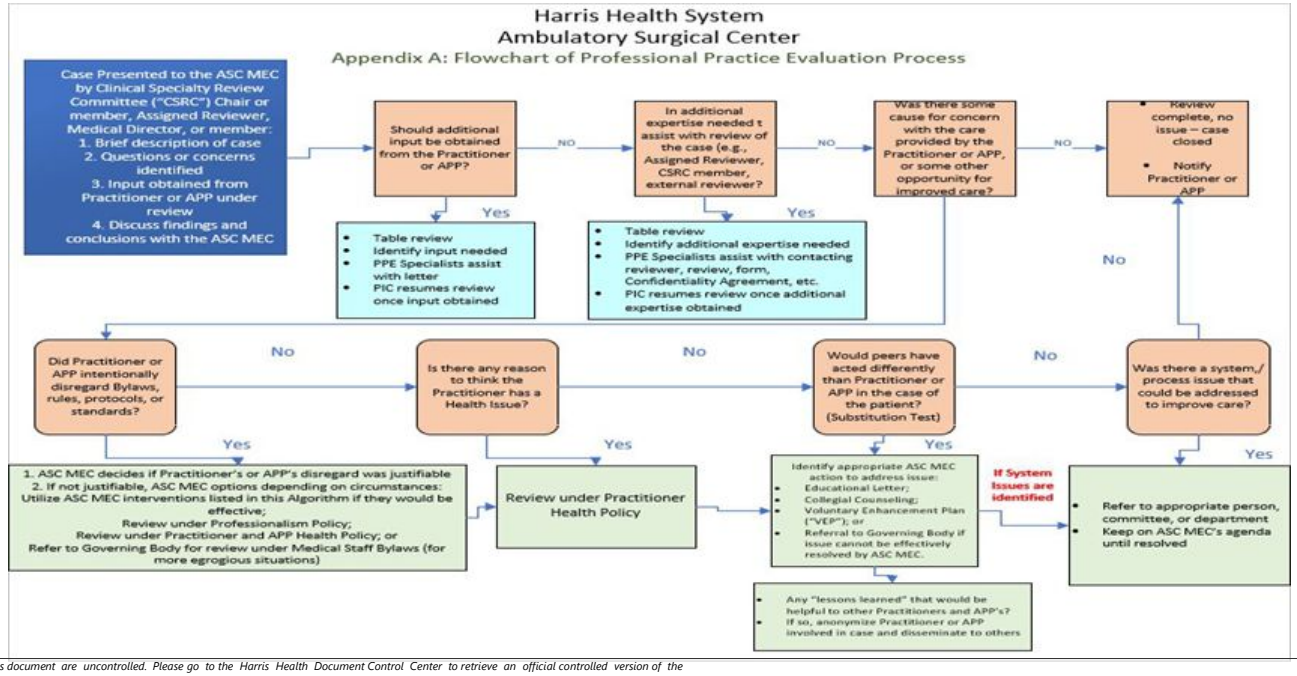
C. In light of the voluntary and non-disciplinary nature of these actions, they do not generally represent matters that require any report to any State Board or to the National Practitioner Data Bank.

Appendix A
Ambulatory Surgical Center at LBJ
Professional Practice Evaluation Process



Harris Health System
Ambulatory Surgical Center
Appendix A: Flowchart of Professional Practice Evaluation Process




Harris Health System
Ambulatory Surgical Center
Appendix A: Flowchart of Professional Practice Evaluation Process
Case Presented to the ASC MEC by Clinical Specialty Review Committee ("CSRC") Chair or member, Assigned Reviewer, Medical Director, or member:
1. Brief description of case
2. Questions or concerns identified
3. Input obtained from Practitioner or APP under review
4. Discuss findings and conclusions with the ASC MEC
Should additional input be obtained from the Practitioner or APP?
NO
In additional expertise needed t assist with review of the case (e.g., Assigned Reviewer, CSRC member, external reviewer?
NO
Was there some cause for concern with the care provided by the Practitioner or APP, or some other opportunity for improved care?
NO
Review complete, no issue – case closed
Notify Practitioner or APP
Yes
Table review
Identify input needed
PPE Specialists assist with letter
PIC resumes review once input obtained
Yes
Table review
Identify additional expertise needed
PPE Specialists assist with contacting reviewer, review, form, Confidentiality Agreement, etc.
PIC resumes review once additional expertise obtained
No
Did Practitioner or APP intentionally disregard Bylaws, rules, protocols, or standards?
No
Is there any reason to think the Practitioner has a Health Issue?
No
Would peers have acted differently than Practitioner or APP in the case of the patient? (Substitution Test)
No
Was there a system,/ process issue that could be addressed to improve care?
Yes
1. ASC MEC decides if Practitioner's or APP's disregard was justifiable
2. If not justifiable, ASC MEC options depending on circumstances: Utilize ASC MEC interventions listed in this Algorithm if they would be effective;
Review under Professionalism Policy;
Review under Practitioner and APP Health Policy; or
Refer to Governing Body for review under Medical Staff Bylaws (for more egregious situations)
Yes
Review under Practitioner Health Policy
Yes
Identify appropriate ASC MEC action to address issue:
Educational Letter;
Collegial Counseling;
Voluntary Enhancement Plan ("VEP"); or
Referral to Governing Body if issue cannot be effectively resolved by ASC MEC.
Yes
If System Issues are identified
Refer to appropriate person, committee, or department
Keep on ASC MEC's agenda until resolved
Yes
Any "lessons learned" that would be helpful to other Practitioners and APP's?
If so, anonymize Practitioner or APP involved in case and disseminate to others

APPENDIX B

CONFLICT OF INTEREST GUIDELINES

Potential Conflicts	Levels of Participation					
	Provide Information	Committee Member			Hearing Panel	Governing Body
		CSRC	ASC MEC	Investigating Committee		
Employment/contract relationship with Harris Health	Y	Y	Y	Y	Y	Y
Self or family member	Y	R	R	N	N	R
Relevant treatment relationship	Y	R	R	N	N	R
Significant financial relationship	Y	Y	Y	N	N	R
Direct competitor	Y	Y	Y	N	N	R
Close friends	Y	Y	Y	N	N	R
History of conflict	Y	Y	Y	N	N	R
Provided care in case under review (but not subject of review)	Y	Y	Y	N	N	R
Involvement in prior VEP or disciplinary action	Y	Y	Y	N	N	R
Formally raised the concern	Y	Y	Y	N	N	R

Y ("Yes") – means the Interested Member may serve in the indicated role; no extra precautions are necessary.

Y ("Yes, with infrequent but occasional limitations") – means the Interested Member may generally serve in the indicated role. It is legally permissible for Interested Members to serve in these roles because of the check and balance provided by the multiple levels of review and the fact that CSRCs and ASC MEC have no disciplinary authority.

In addition, the Chair of each of these committees always has the authority and discretion to recuse a member in a particular situation if the Chair determines that the Interested Member's presence would (i) inhibit the full and fair discussion of the issue before the committee, (ii) skew the recommendation or determination of the committee, or (iii) otherwise be unfair to the Practitioner or APP under review.

N ("No") – means the Interested Member should not serve in the indicated role.

R ("Recuse") – means the Interested Member should be recused, in accordance with the guidelines on the next page.

RULES FOR RECUSAL	
STEP 1 Confirm the conflict of interest	The Committee Chair or Governing Body Chair should confirm the existence of a conflict of interest relevant to the matter under consideration.
STEP 2 Participation by the Interested Member at the meeting	The Interested Member may participate in any part of the meeting that does not involve the conflict-of-interest situation. When the matter implicating the conflict of interest is ready for consideration, the Committee Chair or Governing Body Chair will note that the Interested Member will be excused from the meeting prior to the group's deliberation and decision-making. Prior to being excused, the Interested Member may provide information and answer any questions regarding the following: (i) any factual information for which the Interested Member is the original source; (ii) clinical expertise that is relevant to the matter under consideration; (iii) any policies or procedures that are applicable to the committee or Governing Body or are relevant to the matter under consideration; (iv) the Interested Member's prior involvement in the review of the matter at hand (for example, an Investigating Committee member may describe the Investigating Committee's activities and present the Investigating Committee's written report and recommendations to the Medical Executive Board prior to being excused from the meeting); and (v) how the committee or Governing Body has, in the past, managed issues similar or identical to the matter under consideration.
STEP 3 The Interested Member is excused from the meeting	The Interested Member will then be excused from the meeting (i.e., physically leave the meeting room and/or disconnect from any telephone or other electronic connection) prior to the committee's or Governing Body's deliberation and decision-making.
STEP 4 Record the recusal in the minutes	The recusal should be documented in the minutes of the committee or Governing Body. The minutes should reflect the fact that the Interested Member was excused from the meeting prior to deliberation and decision-making.

REFERENCES/BIBLIOGRAPHY:

Accreditation Association for Ambulatory Health Care (AAAHC), Accreditation Handbook, v443. Quality Category.
Harris Health Ambulatory Surgical Center at LBJ Medical Staff Bylaws, May 2024
Professional Practice Evaluation Policy. Horty, Springer, & Mattern, P.C

OFFICE OF PRIMARY RESPONSIBILITY:

The Ambulatory Surgical Center (ASC) at LBJ

REVIEW/REVISION HISTORY:

Effective Date	Version # (If Applicable)	Review/ Revision Date (Indicate Reviewed or Revised)	Approved by:
	1.0	08/22/2024	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/20/2025	The Ambulatory Surgical Center (ASC) at LBJ Governing Body

TITLE: MEDICAL STAFF PROFESSIONALISM

PURPOSE: To establish guidelines for collegiality, collaboration, and professionalism at the Ambulatory Surgical Center (ASC) at LBJ in order to establish and maintain a culture of quality care and safety.

POLICY STATEMENT:

It is the policy of the Ambulatory Surgical Center (ASC) at LBJ to establish a process that will be used to evaluate and collegially resolve concerns that a physician or Advanced Practice Professional (APP) has engaged in inappropriate conduct. It is also the policy of the ASC to treat each other with respect, courtesy, and dignity, and we ask all to conduct themselves in a professional and cooperative manner.

POLICY ELABORATIONS:

I. REPORTS OF INAPPROPRIATE CONDUCT:

A. DEFINITIONS:

1. **COLLEGIAL COUNSELING**: A formal, planned face-to-face discussion between a physician or APP and the ASC Medical Director.
2. **INAPPROPRIATE CONDUCT**: Conduct defined in Appendix B
3. **INVESTIGATION:** A non-routine, process to review concerns pertaining to a physician or APP. The ASC Medical Director has the authority to initiate and conduct an Investigation. The process to address issues of professional conduct as outlined in this Policy does not constitute an investigation.
4. **PROFESSIONAL PRACTICE EVALUATION (PPE) SPECIALIST(S)**: Staff who support the ASC Medical Director on the Professional Practice Evaluation process generally and the review of issues related to professionalism described in this Policy. This may include Harris Health employees contracted through the Service Level Agreement.
5. **PROFESSIONALISM MANUAL:** Forms, checklists, template letters and other documents that assist with the implementation of this Policy.

Such documents shall be developed and maintained by the PPE Specialists and approved for use by the ASC.

6. **PHYSICIAN/PRACTITIONER AND ADVANCED PRACTICE PROFESSIONAL (APP)**: Shall have the same meaning as those terms are defined in the Medical Staff Bylaws.

7. **SEXUAL HARASSMENT AND OTHER IDENTITY-BASED HARASSMENT**: Conduct defined in Appendix B of this Policy.

B. **REPORTS:**

~~1. Collegial Counseling may only occur after a physician/APP has had an opportunity to provide input regarding a concern. If the Collegial Counseling results from a matter that has been reported to the PPE Specialist and reviewed through this Policy, it shall be followed by a letter that summarizes the discussion and, when applicable, the expectations regarding the physician's future practice at the ASC. A copy of the follow-up letter will be included in the physician/APP's file along with any response that the physician/APP would like to offer. In contrast, informal discussions, mentoring, counseling, sharing of comparative data, and similar efforts that do not meet the criteria for a Collegial Counseling are referred to as Initial Mentoring Efforts. This Policy encourages the use of Initial Mentoring Efforts to assist Practitioners and APPs in continually improving their practices. There is no requirement that input be obtained prior to Initial Mentoring Efforts or that they be documented. However, documentation is recommended particularly if a pattern of behavior may be developing. Any documentation will be maintained in physician/APP's confidential file.~~

~~2.~~1. ASC employees, Practitioners, or APPs who observe, or are subjected to, Inappropriate Conduct by a Practitioner or APP shall report the incident in a timely manner by submitting a report through an approved Harris Health reporting mechanism. Individuals receiving such reports will forward it to the PPE Specialists. The PPE Specialists shall notify the ASC Medical Director of all reported concerns and log them in a confidential peer review

database. Concerns involving Sexual Harassment or Other Identity-Based Harassment will be immediately referred for investigation in accordance with Section KJ.2. of this Policy.

3.2. The PPE Specialists shall follow up with individuals who file a report. A response to the individual reporting concerns about conduct is included in the Professionalism Manual.

C. **RESOLUTION OF MINOR CONCERNS:**

1. A reported minor concern may be resolved without the need for further review under this Policy if the ASC Medical Director determines that the reported concern is minor in nature and there is no history or pattern with the Practitioner or APP in question.

2. For concerns that qualify as minor, the ASC Medical Director may resolve them through the procedure of communicating with the Practitioner or APP about the matter (e.g. "Cup of Coffee" conversation). The purpose of this communication is to make the Practitioner or APP aware that another individual perceived the Practitioner's or APP's behavior as unprofessional and the Practitioner or APP may reflect and self-correct. No conclusions about the Practitioner's or APP's behavior are reached as a result of this process, so there is no need for fact-finding or input from the Practitioner or APP. The Medical Director may choose to follow up with a brief note to the Practitioner or APP memorializing any conversation. The ASC Medical Director will notify the PPE Specialists that a minor concern has been resolved in this manner and complete a "Cup

of Coffee" form. A Form to Document Resolution of Minor Concerns is included in the Professionalism Manual.

3. The PPE Specialists will provide the ASC MEC with periodic reports of minor concerns that have been resolved under this section to allow for oversight of the process and consistency.

D. **PROCEDURE FOR SIGNIFICANT CONCERNS OR A PATTERN HAS DEVELOPED:**

1. The steps set forth below apply to reported concerns about behavior that, as determined by the ASC Medical Director, involve more serious allegations or a pattern of behavior.

2. The ASC Medical Director (or their designees) shall notify the Practitioner or APP that a concern has been raised and that the matter is being reviewed. Generally, this preliminary communication should occur via a brief telephone call, a personal discussion, or e-mail as soon as practical. The Practitioner or APP should be informed that they will be invited to provide input regarding the matter after further review of the reported concern has occurred and before any review by the ASC MEC. The Practitioner or APP should also be reminded to avoid any action that could be perceived as retaliation.

3. A case review form will be sent to the Practitioner or APP's Service Chief by the ~~ASC Medical Director~~ PPE Specialist to inform them of the reported concern and request their review of the matter.

4. The ASC Medical Director (or their designees) shall, in their discretion, interview witnesses or others who were involved in the incident and gather necessary documentation or information needed to assess the reported concern. An Interview Tool for Fact-Finding: Script, Questions, and

Guidance that may be used for such interviews is included in the Professionalism Manual.

5. If an allegation involves Sexual Harassment or other Identity-Based Harassment, fact-finding will occur in accordance with Section KJ.2 of this Policy.

6. Determination by the ASC Medical Director:

   a) Following the investigation, the ASC Medical Director may determine that a reported concern does not raise issues that need to be addressed pursuant to this Policy. In such case, no input regarding the circumstances will be sought from the Practitioner or APP and the matter will be closed. A letter will be sent to the Practitioner or APP notifying them of the reported concern and that the case was closed without further review. The Practitioner or APP and the ASC MEC will be notified of this determination and documentation that the matter was closed will be maintained.

   b) The ASC Medical Director may determine that the reported concern may be addressed through an informal discussion, mentoring, and counseling, or Initial Mentoring Efforts (See Section H). The topic of discussion will be recorded on the case review form.

   ~~b)~~c) The ASC Medical Director may determine that a matter should be reviewed further by the ASC MEC. In such case, the Practitioner's or APP's input and perspective will be obtained as set forth in Section E of this Policy. The matter shall then be referred to the ASC MEC. The PPE Specialists shall prepare a summary report of the

matter for review by the ASC MEC and provide the ASC MEC with all supporting documentation.

~~c~~)d) If an allegation involves Sexual Harassment or Other Identify-Based Harassment, further review will be determined in accordance with Section K~~J~~.2 of this Policy.

E. **OBTAINING INPUT FROM THE PRACTITIONER OR APP:**

1. The ASC Medical Director or PPE Specialists on the behalf of the Medical Director will provide details of the concern, but not a copy of any reported concern, to the Practitioner or APP and ask the Practitioner or APP to provide a written explanation of what occurred and their perspective on the incident. A Cover Letter to Practitioner or APP Seeking Input Regarding Behavior Concern which may be used for this purpose is included in the Professionalism Manual. If an allegation involves Sexual Harassment or other Identity-Based Harassment, obtaining input from the Practitioner or APP will occur in accordance with Section K-J.2. of this Policy

2. Since this Policy does not involve disciplinary action or restrictions of privileges, the specific identity of any individual reporting a concern or otherwise providing information about a matter will not be disclosed to the Practitioner or APP unless the individual consents or the information is later used to support an adverse professional review action that results in a Medical Staff hearing.

3. The ASC Medical Director will remind the Practitioner or APP of the need to maintain confidentiality and the importance of avoiding any actions that could be viewed as retaliation as part of seeking their input. The Cover Letter to Practitioner or APP Seeking Input Regarding Behavior Concern set forth in the Professionalism Manual addresses these issues. If concerns about confidentiality and non-retaliation are more significant, the Practitioner or APP may be required to sign a Confidentiality and Non-Retaliation Agreement (a copy of which is included in the Professionalism

Manual) prior to providing detailed information regarding the concern to the Practitioner or APP.

4. A Practitioner or APP is required to provide written input or attend a meeting as requested by the ASC Medical Director within the time frame specified. Failure to respond within the timeframe result in a review that will proceed without input from the Practitioner or APP.

F. **ASC MEDICAL EXECUTIVE COMMITTEE PROCEDURE:**

1. The ASC MEC shall review, in Executive Session, the summary prepared by the PPE Specialists and supporting documentation, including the Service Chief's review, and response from the Practitioner or APP. If necessary, the ASC MEC may also meet with the individual who submitted the report and any witnesses to the incident. The ASC MEC may consult with or include in the review another physician or APP or any other individual who would assist in the review.

2. If either the ASC MEC or the Practitioner or APP believes it would be helpful prior to the ASC MEC concluding its review and making a determination, a meeting may be held between the Practitioner or APP and the ASC MEC to discuss the circumstances further and obtain additional facts. At its discretion, the ASC MEC may designate one or more committee members to attend the meeting rather than the full committee, regardless of who requested the meeting. The ASC MEC may also obtain additional written input from the Practitioner or APP as set forth in Section D of this policy. If an allegation involves Sexual Harassment or other

Identity-Based Harassment, this meeting will occur in accordance with Section ~~J~~K.2. of this Policy.

3. A Practitioner or APP who refuses to provide information or meet with the ASC MEC will be addressed as set forth in Section D of this policy.

G. **ASC MEC DETERMINATION:**

1. After review of relevant information, including input from the Practitioner or APP, the ASC MEC may:

   a) Determine that no further review or action is required;

   b) Send the Practitioner or APP an Educational Letter, providing guidance and counsel;

   c) Engage in Collegial Counseling with the Practitioner or APP and provide education and coaching as described in Section H of this Policy (a Collegial Counseling Checklist and Follow-Up Letter to Collegial Counseling are included in the Professionalism Manual);

   d) Develop a Voluntary Enhancement Plan for Conduct (VEP), as described in Section I~~H~~ of this Policy (an Implementation Issues Checklist for VEPs for Conduct is included in the Professionalism Manual); or

   e) Refer the matter for Corrective Action as set forth in the ASC Medical Staff Bylaws.

2. A review conducted by the ASC MEC or by any individual pursuant to this Policy shall not constitute an Investigation.

3. If additional reports of Inappropriate Conduct are received concerning a Practitioner or APP, the ASC MEC may continue to use the collegial and progressive steps outlined in this Policy as long as it believes that there is a reasonable likelihood that those efforts will resolve the concerns.

4. The ASC MEC may determine to address the conduct concerns through the Practitioner Health Policy if it believes that there may be a legitimate, underlying health issue that is causing the concerns and the review process

outlined in the Practitioner/APP Health Policy is more likely to successfully resolve the concerns.

H. **COLLEGIAL COUNSELING:**

1. Collegial Counseling may only occur after a physician/APP has had an opportunity to provide input regarding a concern. If the Collegial Counseling results from a matter that has been reported to the PPE Specialist and reviewed through this Policy, it shall be followed by a letter that summarizes the discussion and, when applicable, the expectations regarding the physician's future practice at the ASC. A copy of the follow-up letter will be included in the physician/APP's file along with any response that the physician/APP would like to offer. In contrast, informal discussions, mentoring, counseling, sharing of comparative data, and similar efforts that do not meet the criteria for a Collegial Counseling are referred to as Initial Mentoring Efforts. This Policy encourages the use of Initial Mentoring Efforts to assist Practitioners and APPs in continually improving their practices. There is no requirement that input be obtained prior to Initial Mentoring Efforts or that they be documented. However, documentation is recommended particularly if a pattern of behavior may be developing. Any documentation will be maintained in physician/APP's confidential file.

~~H.~~I. **VOLUNTARY ENHANCEMENT PLAN:**

1. The ASC MEC may determine it is necessary to develop a Voluntary Enhancement Plan (VEP) for the Practitioner or APP. One or more of the ASC MEC members will discuss the VEP with the Practitioner or APP to help ensure a shared and clear understanding of the elements of the VEP. The VEP will be presented in writing, with a copy being placed in the Practitioner's or APP's file, along with any statement the Practitioner or APP would like to offer.

2. If a Practitioner or APP agrees to participate in a VEP developed by the ASC MEC, such agreement will be documented in writing. If a Practitioner

or APP disagrees with a recommended VEP developed by the ASC MEC, the Practitioner or APP is under no obligation to participate. In such a case, the ASC MEC cannot compel the Practitioner or APP to agree with the VEP. Instead, the ASC MEC will refer the matter review and action pursuant to the Medical Staff Bylaws.

3. A VEP for conduct may include, but is not limited to, one or more of the actions in this Section. None of these actions entitles the Practitioner or APP to a hearing or appeal as described in the Medical Staff Bylaws, nor do they require that reports be made to any state licensing board or the National Practitioner Data Bank. A VEP Options for Conduct – Implementation Issues Checklist that may be used to assist with implementation of the following VEP options is included in the Professionalism Manual

   a) Within a specified period of time, the Practitioner or APP, must arrange for education or CME related to behavioral matters of a duration and type approved by the ASC MEC;

   b) The Practitioner or APP may be invited to meet with a designated group to discuss the concerns with the Practitioner's or APP's conduct and the need to modify the conduct. An ad hoc group may include any combination of current or past Medical Staff Leaders, Harris Health leaders, outside consultants, if the ASC MEC determines that involvement is reasonably likely to impress upon the Practitioner or APP involved the seriousness of the matter and the necessity for the Practitioner's or APP's conduct to improve. A letter outlining the discussion and expectations for conduct shall be sent to the Practitioner or APP after the meeting;

   c) The ASC MEC may recommend that the Practitioner or APP be required to meet periodically with one or more medical staff leaders or a mentor designated by the ASC MEC. The purpose of these meetings is to provide input and updates on the Practitioner's or

APP's performance, as well as to offer assistance and support with any challenging issues the Practitioner or APP may be encountering;

d) The ASC MEC may recommend that the Practitioner or APP review selected literature concerning the established connection between behavior and patient care and safety and then provide a report to the ASC MEC summarizing the information reviewed and how it can be applied to the individual's practice;

e) The ASC MEC may recommend that the Practitioner or APP complete a behavior modification course that is acceptable to the ASC MEC. The cost of this external assistance shall be borne by the Practitioner or APP, unless the ASC MEC determines otherwise.;

f) The ASC MEC may develop a personal code of conduct for the Practitioner or APP, which provides specific guidance regarding the expectations for future conduct and outlines the specific consequences of the Practitioner's or APP's failure to abide by it; and/or

g) Elements not specifically listed above may be included in a VEP. The ASC MEC has wide latitude to tailor VEPs to the specific concerns identified, always with the objective of helping the Practitioner or APP to improve his or her performance and to protect patients and staff.

~~I.~~J. GOVERNING BODY

The Governing Body shall receive reports and recommendations from the ASC MEC as outlined in the ASC Governing Body Bylaws and ASC Medical Staff Bylaws.

~~J.~~K. REVIEW OF REPORTS OF SEXUAL HARASSMENT AND OTHER IDENTITY-BASED HARASSMENT:

1. Sexual Harassment and other Identity-Based Harassment is defined in Appendix B of this Policy.

2. All reports of potential Sexual Harassment and other Identity-Based Harassment involving patients will be immediately referred to the Practitioner or APP's affiliated medical school's Title IX Coordinator or designee to investigate. If the Practitioner or APP is not affiliated with a medical school, or a report involves a workforce member, then the report of potential Sexual Harassment and other Identity-Based Harassment will be immediately referred to Harris Health's Office of Corporate Compliance and Human Resources (HR) Department to investigate. Upon completion of the investigation, the outcome of the investigation conducted by the affiliated medical school or the Office of Corporate Compliance will be communicated to the ASC MEC, with an opportunity for the ASC MEC to ask questions or seek clarity from the investigating body.

3. While a Practitioner or APP may be asked to voluntarily refrain from exercising clinical privileges pending the review of any behavioral matter under this Policy, particular attention will be paid to whether it is necessary to utilize such a temporizing safeguard while an allegation of Sexual Harassment or other Identity-Based Harassment is being reviewed.

~~K.~~L. ADDITONAL PROVISIONS GOVENING THE PROFESSIONALISM REVIEW PROCESS:

1. Maintaining confidentiality is a fundamental and essential element of an effective professional practice evaluation process.

2. All documentation that is prepared in accordance with this Policy shall be managed in a manner reasonably calculated to assure privacy and shall be maintained in appropriate Medical Staff files. All documents will be conspicuously marked with the notation "Confidential PPE/Peer Review" or words to that effect, consistent with their privileged and protected status

under state or federal law. Failure to mark documents in this manner shall not be viewed as an indication that the document is not privileged.

3. Telephone and in-person conversations should take place at appropriate times and in locations to minimize the risk of a breach of confidentiality.

4. Electronic correspondence may be used to communicate between individuals participating in the professionalism review process, including with the Practitioner or APP in question. All correspondence should include a standard convention, such as "Confidential PPE/Peer Review Communication," in the subject line. Correspondence should not be sent to non-ASC accounts unless the e-mail directs recipients to check their institutional account.

5. All individuals involved in the review process will maintain confidentiality of the process.

6. The Practitioner or APP under review must maintain all information related to the review in a strictly confidential manner. The Practitioner or APP may not disclose information to, or discuss it with, anyone outside of the review process set forth in this Policy without obtaining the written permission of Harris Health, except for any legal counsel who may be advising the Practitioner or APP. Violations of this provision will be reviewed under this Policy.

7. Correspondence that includes a deadline for a response is mailed or e-mailed to a Practitioner, a phone call should be made to alert the Practitioner or APP that the correspondence is being sent. The intent of any such conversation is to make the Practitioner or APP aware of the correspondence so the deadline is not missed. However, failure to communicate a deadline shall not be cause for the Practitioner or APP to miss a deadline.

8. This Policy outlines collegial and progressive steps (e.g., counseling, warnings, meetings, and behavior modification education) that can be taken to address concerns about Inappropriate Conduct by Practitioners or APPs. However, a single incident of Inappropriate Conduct or a pattern of

Inappropriate Conduct may be of such concern that more significant action is required. Therefore, nothing in this Policy precludes an immediate referral of a matter being addressed through this Policy or the elimination of any particular steps in this Policy, to review pursuant to the ASC Medical Staff Bylaws.

9. To promote the collegial and educational objectives of this Policy, all discussions and meetings with a Practitioner or APP shall generally involve only the Practitioner or APP and the appropriate ASC personnel. No counsel representing the Practitioner or APP or the ASC shall attend any of these meetings. In their discretion, the ASC may permit a Practitioner or APP to invite another Practitioner or APP to the meeting. In such case, the invited Practitioner or APP may not participate in the discussion or in any way serve as an advocate for the Practitioner or APP under review, must sign a Confidentiality Agreement, and may be required to leave the meeting at any time.

10. Practitioners or APPs may not create an audio or video recording of a meeting. If a recording is made, the recording shall be destroyed. The ASC may require any and all portable electronic devices, e.g., tablets, mobile cellular devices, laptops, be left outside the meeting room. In exceptional circumstances, the ASC may record a meeting to prepare accurate minutes for an interview summary. Once the interview summary document is prepared, any such recording shall be destroyed.

11. The ASC shall partner with its medical school affiliates for appropriate education of Practitioners and APPs regarding appropriate professional behavior. The ASC, through its Service Level Agreement will partner with the appropriate Harris Health departments to educate employees and other ASC personnel awareness of this Policy, and encourage the prompt reporting of Inappropriate Conduct.

12. Copies of letters sent to the Practitioner or APP as part of the efforts to address the Practitioner's or APP's conduct shall be placed in the Practitioner's or APP's confidential file. The Practitioner or APP shall be

given an opportunity to respond, in writing, and the Practitioner's or APP's response shall also be kept in the Practitioner's or APP's confidential file.

13. If a matter involves both clinical and behavioral concerns, the ASC MEC shall coordinate reviews pursuant to applicable policy(ies) and address such matters with the Practitioner or APP.

14. Except as noted below, a physician who has a supervisory or collaborative relationship with an Advanced Practice Professional for state licensure purposes shall be kept apprised of any concerns that are reviewed pursuant to this Policy involving the Advanced Practice Professional. Without limiting the oversight of the collaborating physician, they will be copied on all correspondence that an Advanced Practice Professional is sent under this Policy and may be invited to participate in necessary meetings or interventions. The collaborating physician shall maintain, in a confidential manner, all information related to reviews under this Policy and may be required to sign a Confidentiality Agreement. Notification to the collaborating physician as described in this Section is not required, or may be delayed, if the individual or committee conducting the review determines that notification would be inconsistent with a fair and effective review.

15. The ASC MEC is responsible for the professionalism/quality assurance process described in this Policy, subject to the oversight of the Governing Body. To promote a prompt and effective review process, the ASC MEC may expressly delegate to the PPE Specialist(s) the authority to perform functions described in this Policy on behalf of the ASC MEC. Actions taken by the PPE Specialist(s) will be reported to and reviewed by the ASC MEC as set forth in this Policy.

    a) When a function under this Policy is to be carried out by one of the individuals identified in the prior subsection, by an ASC leader, a Medical Staff member, or the ASC MEC, the individual may delegate performance of the function to a qualified designee who is a Practitioner, APP, or ASC employee. Any such designee must treat and maintain all information in a strictly confidential manner and is bound by all other terms, conditions, and requirements of this Policy.

In addition, the delegating party is responsible for ensuring that the designee appropriately performs the function delegated. Any documentation created by the designee are records of the committee that is ultimately responsible for the review in a particular matter.

b) When an individual assigned a function under this Policy is unavailable or unable to perform that function, one or more ASC MEC member may perform the function personally or delegate it to another appropriate individual as set forth in this Policy.

16. While every effort will be made to comply with provisions of this Policy, substantial compliance is required. Technical or minor deviations from the procedures set forth within this Policy do not invalidate any review or action taken.

17. Once a professionalism concern is resolved, the PPE Specialists should complete the Professionalism Issue Summary Form and maintain this within the Practitioner's or APP's confidential file. These forms facilitate the identification of trends, inform the determinations made by the ASC MEC when assessing professionalism issues, and supplement both the ongoing performance data review and reappointment processes. A Professionalism Issue Summary Form is included in the Professionalism Manual.

18. The ASC MEC shall prepare reports at least annually that provide aggregate information regarding the professionalism review process (e.g., numbers of concerns reviewed by department or specialty; the types of dispositions for those concerns; etc.). These reports should be disseminated to all Practitioners and APPs at the ASC, and the Governing Body for the purposes of reinforcing the purpose of this Policy and permitting appropriate oversight. A sample Summary Report for Professionalism Review Activities to Be Provided to All Practitioners, APPs, MEC, and Governing Body is included in the Professionalism Manual.

19. At any point in the review process described in this Policy, the ASC MEC may ask a Practitioner or APP to voluntarily refrain from exercising clinical

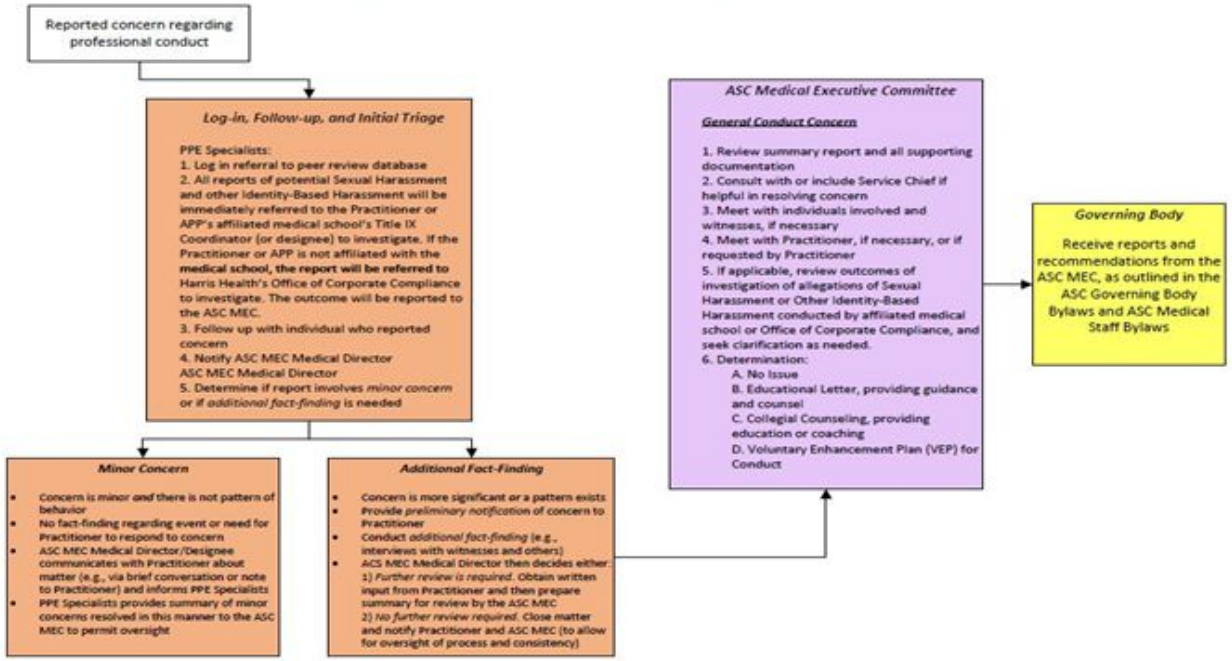
privileges while the review proceeds. As an alternative, the Practitioner or APP may also agree upon practice conditions that will protect the Practitioner or APP, patients, and the ASC during the review process. Prior to any such action, the Practitioner or APP shall be given the opportunity to discuss these issues with the ASC MEC or its representatives and provide written input regarding them.

a) These actions are not considered to be disciplinary actions and do not imply any admission by the Practitioner or APP or final finding of responsibility for the concerns that have been raised. They are temporary precautions and reflect professionalism and cooperation with the review process.

b) In light of the voluntary and non-disciplinary nature of these actions, they do not generally represent matters that require any report to any State Board or to the National Practitioner Data Bank.

Appendix A

Harris Health System
Ambulatory Surgical Center
Appendix A: Review Process for Concerns Regarding Professional Conduct



Printe
document. https://sp2019apps.hchd.local/sites/dcc

APPENDIX B

DEFINITION OF INAPPROPRIATE CONDUCT AND SEXUAL HARASSMENT/OTHER IDENTITY-BASED HARASSMENT

1. ***"Inappropriate Conduct"*** means behavior that, as determined by the ASC MEC, adversely affects the healthcare team's ability to work effectively and/or has a negative effect on the communication and collaboration necessary for quality and safe patient care. To aid in both the education of Practitioners and APPs and the enforcement of this Policy, ***"Inappropriate Conduct"*** includes, but is not limited to:

   a) Abusive or threatening language directed at patients, nurses, students, volunteers, visitors, ASC Workforce members, Practitioners, or APPs;

   b) Degrading, demeaning, or condescending comments regarding patients, families, nurses, Practitioners, APPs, ASC at LBJ personnel, or the ASC at LBJ;

   c) Refusal or failure to answer questions, or return phone calls, or pages in a timely manner as defined in the Medical Staff Bylaws documents or other applicable policies;

   d) Intentional misrepresentation to the ASC administration, Medical Staff leaders, other Practitioners or APPs, or their representatives, in an attempt to gain a personal benefit or to avoid responsibility for an action taken;

   e) Offensive language (which may include profanity or similar language) while at the ASC or while speaking with patients, nurses, or other ASC personnel;

   f) Retaliating against any individual who may have reported a quality or behavior concern about a Practitioner or APP, provided information related to such a matter, or otherwise been involved in the professional practice evaluation/peer review process in any way (this means a Practitioner or APP may not, under any circumstances, approach and

discuss the matter with any such individual, nor may the Practitioner or APP engage in any other retaliatory or abusive conduct such as confronting, ostracizing, or discriminating against such individual);

g) Unprofessional physical contact with another individual or other aggressive behavior that is threatening or intimidating;

h) Throwing an object of any kind, including but not limited to any medical/surgical instrument or supply;

i) Repeatedly failing to maintain and renew in a timely manner all credentials required by the Medical Staff Bylaws;

j) Derogatory comments about the quality of care being provided by the ASC, another Practitioner or APP, or any other individual outside of appropriate Medical Staff or ASC administrative channels;

k) Unprofessional medical record entries impugning the quality of care being provided by the ASC, Practitioners or APPs, or any other individual, or criticizing the ASC or the ASC's policies or processes, or accreditation and regulatory requirements;

l) Altering or falsifying any medical record entry or document;

m) Completing medical record entries based on a template without considering the care actually provided to the patient, or using the "copy and paste" or "pull forward" functions of the medical record to populate

fields without verifying that the information is accurate for the patient in question;

n) Refusal or failure to use or use properly documentation technology (e.g., CPOE, EHR, and other approved technology);

o) Unprofessional access, use, disclosure, or release of confidential patient information;

p) Audio, video, or digital recording that is not consented to by others present, including patients and other members of the care team;

q) Use of social media in a manner that involves Inappropriate Conduct as defined in this Policy or other Medical Staff or ASC policies;

r) Disruption of ASC operations, Medical Staff committees, or departmental affairs;

s) Refusal to abide by Medical Staff requirements as delineated in this Policy, the Medical Staff Bylaws, Rules and Regulations, or other Medical Staff policies including, but not limited to, medical recordkeeping, other patient care responsibilities, failure to participate on assigned committees, failure to cooperate with utilization oversight activities, and an unwillingness to work cooperatively and harmoniously with other members of the Medical Staff and ASC employees;

t) Conduct that is inconsistent with the ethical obligations of health care professionals; and/or

u) Engaging in ***Sexual Harassment or other Identity-Based Harassment*** as defined in Section 2 of this Appendix.

~~u)~~v) The refusal or failure to provide or utilize appropriate language access services for patients whose language identified as a language other than English in the patient's medical record.

ADDITIONAL NOTE REGARDING INAPPROPRIATE CONDUCT:

A. This policy is not intended to interfere with a practitioner's or app's ability to express, in a professional manner and in an appropriate forum:

1. Opinions on any topic that are contrary to opinions held by other Practitioners or APPs, Medical Staff Leaders, or ASC personnel;
2. Disagreement with any Medical Staff Bylaws or ASC policies, procedures, proposals, or decisions; or
3. Constructive criticism of the care provided by any Practitioner or APP, nurse, or other ASC personnel.

B. **Sexual harassment and other identity-based harassment are a form of inappropriate conduct, and include verbal or physical conduct that:**

1. Are unwelcome and offensive to an individual who is subjected to it or who witnesses it;
2. Could be considered harassment from the objective standpoint of a "reasonable person"; and
3. Is covered by state or Federal laws governing discrimination. This includes, but is not limited to, sexual harassment and racial, ethnic, or religious discrimination.

Tests and standards used by courts to determine if conduct violates federal or state law (e.g., Title VII of the Civil Rights Act) are ***not*** dispositive in determining whether conduct is Sexual Harassment or Other Identity-Based Harassment for purposes of this Policy. Instead, the standard set forth in this section shall govern, as interpreted by the Medical Executive Committee, and/or the Governing Body. The intent of this provision is to create higher expectations for professional behavior by Practitioners and APPs than the minimum required by federal or state law.

Sexual Harassment and Other Identity-Based Harassment include all of the following behaviors:

Verbal: innuendoes, epithets, derogatory slurs, off-color jokes, propositions, graphic commentaries, threats, and suggestive or insulting sounds.

Visual/Non-Verbal: derogatory posters, cartoons, or drawings; suggestive objects or pictures; leering; and obscene gestures.

Physical: unwanted physical contact, including touching, interference with an individual's normal work movement, and assault.

Quid Pro Quo: suggesting that submission to an unwelcome sexual advance will lead to a positive employment action or avoid a negative employment action.

Retaliation: retaliating or threatening retaliation as a result of an individual's complaint regarding harassment.

REFERENCES/BIBLIOGRAPHY:

Accreditation Association for Ambulatory Health Care (AAAHC), Accreditation Handbook, v443. Quality Category.
Harris Health Ambulatory Surgical Center at LBJ Medical Staff Bylaws, May 2024
Professional Practice Evaluation Policy. Horty, Springer, & Mattern, P.C

OFFICE OF PRIMARY RESPONSIBILITY:

The Ambulatory Surgical Center (ASC) at LBJ

REVIEW/REVISION HISTORY:

Effective Date	Version # (If Applicable)	Review/ Revision Date (Indicate Reviewed or Revised)	Approved by:
	1.0	08/22/2024	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Revised / Approved 02/20/2025	The Ambulatory Surgical Center (ASC) at LBJ Governing Body

TITLE: INCIDENT REPORTING

PURPOSE: To provide guidance regarding the reporting and response of Incidents involving patients, visitors, or Workforce members, which are inconsistent with the standard of care, and/or the routine operations of the Ambulatory Surgical Center (ASC) at LBJ.

POLICY STATEMENT:

All incidents including injuries and hazards involving patients, visitors, and Workforce members that are inconsistent with the standard of care of a patient or routine operations of Ambulatory Surgical Center (ASC) at LBJ shall be reported using the Harris Health electronic incident reporting system (eIRS) pursuant to the Letter of Agreement between Harris Health and the Ambulatory Surgical Center (ASC) at LBJ. The ASC does not tolerate retaliation against Workforce members who report Incidents.

POLICY ELABORATIONS:

I. DEFINITIONS:

A. **EVENT:** A patient care event that is unfavorable, undesirable, and usually unanticipated that causes death or serious injury, or the risk thereof. Adverse events may result from unintentional acts or omissions. Events may include, but are not limited to:

1. Patient falls;
2. Medication errors;
3. Procedural errors/complications;
4. Completed or attempted suicides;
5. Iatrogenic injuries, i.e., injuries due to medical treatment or procedure;
6. Failure to make a timely diagnosis;
7. Untimely implementation of appropriate therapeutic intervention; and
8. Missing patient events.

B. **ADVANCED PRACTICE PROFESSIONAL (APP):** An individual who holds a state license in their profession as well as other education credentials attesting to training and qualifications to provide services in one or more of the following categories: Physician Assistant (PA), Certified Registered Nurse Anesthetist (CRNA), Nurse Practitioner (NP) or Clinical Nurse Specialist (CNS), Optometrist (OD), Certified Nurse Midwife (CNM), Clinical Psychologist, Registered Dietician, and Clinical Pharmacist.

C. **INCIDENT:** An accident or injury that occurs within Harris Health staffed locations that is inconsistent with the standard of care of a patient or routine operations of Harris Health which may result in an unanticipated harm or injury to patients, visitors, affiliates, employees, and others. "Incident" shall include, but is not limited to events that are inconsistent with any Harris Health policy or procedures or non-anticipated and non-routine patient, employee, affiliate, contractor, visitor, volunteer or other injuries resulting from accidents or errors.

D. **MEDICAL STAFF:** All physicians, dentists, podiatrists and oral-maxillofacial surgeons who are appointed to the Medical Staff and who either: (i) hold a faculty appointment at Baylor College of Medicine and/or The University of Texas Health Science Center at Houston; or (ii) are employed by ASC to provide healthcare services at designated ASC Facilities.

E. **GOOD CATCH:** An event or situation that could have resulted in an accident, injury, or illness, but did not, either by chance or through timely intervention. An example of a Good Catch would be a surgical or other procedure almost performed on the wrong patient due to lapses in verification of patient identification but caught at the last minute by chance. Good Catches are opportunities for learning and afford the chance to develop preventive strategies and actions. A Good Catch will receive the same level of scrutiny as Incidents that result in actual injury.

F. **SERIOUS REPORTABLE EVENT:** An event that can result in death, loss of a body part, serious harm/injury/disability, loss of bodily function, or require major intervention for correction. It is also considered to be an event that is unambiguous, largely preventable, and serious, as well as adverse, indicative of a problem in a healthcare setting's safety systems.

H. **WORKFORCE:** The employees, medical staff, trainees, contractors, volunteers and vendors.

II. GENERAL PROVISIONS:

A. All Workforce members are responsible for safety and reporting safety concerns at the direction of Harris Health Risk Management and Patient Safety as follows. Risk Management & Patient Safety Department will maintain the eIRS System. All incident reports will be reviewed and acted upon immediately and appropriately by the unit Nurse Manager. When a Serious Reportable Event occurs (see Appendix A), the Nurse Manager will provide a phone call to the Risk Management and

Patient Safety Department. The Risk Management and Patient Safety Department will request follow up from the appropriate ASC team member(s). The Risk and Patient Safety Department is responsible for external reporting related to device issues that may require FDA Medwatch reporting or Texas Preventable Adverse Event reporting as appropriate.

B. Workforce Members shall immediately notify their Nurse Manager of all Incidents and complete an incident report at the time they become aware of or witness an incident, no later than the end of shift. An incident report must be completed for all incidents regardless of severity.

C. The ASC's unit Nurse Manager must immediately notify a member of the Risk Management and Patient Safety Department for any incident that is a Serious Safety Event/Safety Event or Serious Reportable Event, an Incident that results in harm or a situation that poses a high risk to the organization, patients, visitors or Workforce Members. The Leadership Team Member will ensure all incident reports are acted upon appropriately. This includes documenting steps taken to prevent recurrence. Requests for feedback should be completed by the Nurse Manager within seven calendar days, unless otherwise requested by the Risk Management and Patient Safety Department. If feedback is not received within seven days escalation to the ASC Administrator will occur.

III. GENERAL PROCEDURE:

A. The Workforce member who discovers or witnesses an Incident involving a patient shall immediately notify the patient's care team. Regardless of the severity of an Incident, the Workforce member must immediately notify their Nurse Manager at the time of the Incident:

1. A foreign object accidently left in a patient during a procedure and/or
2. A patient death or serious disability associated with the use or function of a device designed for patient care that is used or functions other than as intended.

B. The Workforce member who discovers or witnesses an Incident must submit an Incident Report in the eIRS system before they leave at the end of their shift or use a downtime form if the eIRS system is not available. The incident report shall include all pertinent facts specific to the event. The cause of the event should be noted whenever possible.

C. Workforce members are accountable for ensuring all Incidents are documented in eIRS.

D. For Incidents involving patients, an objective, factual description of the Incident and care provided should be written in the medical record. However, the reporter must **not** write in the medical record that the Incident was reported in eIRS. Questions should be directed to the Risk Management and Patient Safety Department at safety1st@harrishealth.org or by contacting Risk Management and Patient Safety through the page operator.

E. Good Catches should be entered by any Workforce member who becomes aware of the Good Catch so that the ASC can review the event and learn from processes that worked successfully and those that may need revision.

IV. DOCUMENTATION GUIDELINES AND CONFIDENTIALITY

A. Incident reports should be completed as thoroughly as possible and should include objective and relevant information

B. For Incidents involving a patient, information connected with the incident that affect the patient's condition or care should be noted in the patient's medical record. Any information in the medical record regarding the Incident should be limited to clinically relevant information. Other information such as suggestions for improvement, administrative issues, system issues, or other issues should be included in an eIRS.

C. Incident reports, attachments, and all investigatory documentation relating to an Incident are confidential, legally privileged, and protected from disclosure pursuant to the Texas Occupations Code and Texas Health and Safety Code. Unless explicitly authorized by the Risk Management and Patient Safety Department, Incident reports or documentation relating to an Incident cannot be:

1. Printed;
2. Emailed or distributed (including screen shots);
3. Photocopied;
4. Placed in a patient's medical record;
5. Referred to in a patient's medical record;
6. Left in a patient's room; or
7. Shared with personnel other than those specified by the reporting procedure or otherwise authorized.

D. Workforce members are prohibited from providing incident reports to a patient, visitor, employee, or other individual that requests a copy of an incident report. If such request is made the request should be directed to the Risk Management and Patient Safety Department or the Harris County Attorney's Office.

REFERENCES/BIBLIOGRAPHY:

The Ambulatory Surgical Center at LBJ Quality Improvement Program

The Harris Health Patient Safety Plan

National Quality Forum, ~~–~~Updating the Serious Reportable Events (SRE) List | NQF~~http://www.qualityforum.org/topics/sres/serious_reportable_events.aspx~~

25 Texas Administrative Code (TAC) § 135.26

42 Code of Federal Regulations (C.F.R.) §416.50(a).

OFFICE OF PRIMARY RESPONSIBILITY:

The Ambulatory Surgical Center (ASC) at LBJ

REVIEW/REVISION HISTORY:

Effective Date	Version # (If Applicable)	Review/ Revision Date (Indicate Reviewed or Revised)	Approved by:
08/05/2016	1.0	08/05/2016	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 03/29/2018	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/14/2019	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/13/2020	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/25/2021	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/17/2022	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Revised / Approved 02/16/2023	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/22/2024	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/20/2025	The Ambulatory Surgical Center (ASC) at LBJ Governing Body

Formatted: Indent: Left: 0.05", Right: 1.53", Space Before: 0 pt, Line spacing: Multiple 1 li

Appendix A

National Quality Forum
Serious Reportable Events

https://www.qualityforum.org/en-us/key-initiatives/updating-the-serious-reportable-events-sre-list~~(http://www.qualityforum.org/topics/sres/serious_reportable_events.aspx),~~ Serious Reportable Events must be reported into the eIRS system. Serious Reportable Events include, but are not limited to:

1. Surgical or Invasive Procedure Events
   a. Surgery or other invasive procedure performed on the wrong site
   b. Surgery or other invasive procedure performed on the wrong patient
   c. Wrong surgical or other invasive procedure performed on a patient
   d. Unintended retention of a foreign object in a patient after surgery or other invasive procedure
   e. Intraoperative or immediately postoperative/post procedure death in an ASA Class 1 patient
2. Product or Device Events
   a. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting
   b. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended
   c. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting
3. Patient Protection Events
   a. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person
   b. Patient death or serious injury associated with patient elopement (disappearance)
   c. Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting
4. Care Management Events
   a. Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
   b. Patient death or serious injury associated with unsafe administration of blood products
   c. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting

d. Death or serious injury of a neonate associated with labor or delivery in a low- risk pregnancy
e. Patient death or serious injury associated with a fall while being cared for in a healthcare setting
f. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting
g. Artificial insemination with the wrong donor sperm or wrong egg
h. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen
i. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results

5. Environmental Events
   a. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting
   b. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances
   c. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting
   d. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting
6. Radiologic Events
   a. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area
7. Potential Criminal Events
   a. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
   b. Abduction of a patient/resident of any age
   c. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting
   d. Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting

TITLE: FIRE DRILL/ALARM PROCEDURE

PURPOSE: To establish the protocol to be followed in the event of a fire alarm or fire drill at the Ambulatory Surgical Center (ASC) at LBJ.

POLICY STATEMENT:

To protect Workforce members of the Ambulatory Surgical Center (ASC) at LBJ ("ASC"), and patients of the ASC from a fire, the ASC will follow Harris Health's Emergency Preparedness Guide and will treat every fire alarm as a serious event.

I. PROCEDURE:

A. If a fire alarm ("Code Red") is triggered in the ASC or if a fire is identified in the ASC, the following actions must be taken pursuant to recommendations by the Houston Fire Department (**RACE**):

1. **R**escue patients, evacuate to a safe area;
2. **A**larm - Pull nearest fire alarm, dial ext. *37800, give exact location and announce to the ASC that a "Code Red" exists;

   Note: if you are unable to contact the operator, dial the Houston Fire Department at 911. Do not panic or shout fire.

3. **C**ontain fire, close doors/windows; and
4. **E**xtinguish/Evacuate department/unit.

B. When operating the fire extinguisher, workforce members must adhere to the following procedure (**PASS**):

1. **P**ull the pin;
2. **A**im at the base of the fire;
3. **S**queeze the trigger; and
4. **S**weep from side to side.

C. Documentation Requirements after a Fire Drill or Fire Alarm:

1. The ASC Administrator or designee must document the ASC's response to a drill or actual fire on the Code Red Form (attached here to as Attachment A).
2. The ASC Administrator or designee must complete the appropriate form(s) if a patient, visitor, or a Workforce member is injured.
3. If an actual fire incident occurs at the ASC, the Administrator or designee shall submit a Texas Department of State Health Services Ambulatory Surgical Center Incident Reporting Form within ten (10) business days of the incident.

REFERENCES/BIBLIOGRAPHY:

AAAHC V443
Emergency Preparedness Guide

BTGH Fire Safety Plan Policy FP

Texas Department of State Health Services Ambulatory Surgical Center Incident Reporting Form

OFFICE OF PRIMARY RESPONSIBILITY:

The Ambulatory Surgical Center (ASC) at LBJ

REVIEW/REVISION HISTORY:

Effective Date	Version # (If Applicable)	Review/ Revision Date (Indicate Reviewed or Revised)	Approved by:
8/5/16	1.0		The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/14/2019	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/13/2020	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/25/2021	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/17/2022	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Revised / Approved 02/16/2023	The Ambulatory Surgical Center (ASC) at LBJ Governing Body

		Revised / Approved 02/22/2024	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Revised / Approved 02/20/2025	The Ambulatory Surgical Center (ASC) at LBJ Governing Body

ATTACHMENT "A"

Link to the Harris Health System Code Red Report form

ATTACHMENT "B"

TEXAS DEPARTMENT OF STATE HEALTH SERVICES AMBULATORY SURGICAL CENTER INCIDENT REPORTING FORM

Name of Facility: _____

Facility License #: _____

Telephone: _____

Contact person(s): _____

Reporting Information – (incidents must be reported within 10 business days):

1. Date of this report: _____
2. Date of incident: _____
3. Type of incident:

□ Death of a patient while under the care of the ASC

□ The transfer of a patient to a hospital

□ Patient development of complications within 24 hours of discharge from the ASC resulting in admission to a hospital

□ A patient stay exceeding 23 hours

□ Occurrence of fire in the ASC

□ Theft of drugs and/or diversion of controlled drugs

4. Summary of reportable incident; what happened and how it was handled *(attach a separate sheet if necessary)*:

_____
_____
_____
_____
_____
_____

Return this form and any attachments within 10 business days of the incident to: Texas Department of State Health Services Regulatory Licensing Unit - Facility Licensing Group Attn: Consolidated Programs Delivery Code 2835 PO Box 149347 Austin, Texas 78714-9347 Fax: (512) 834-451

TITLE: IMMEDIATE OR TIMELY RETURN OF THE PATIENT TO THE OPERATING ROOM

PURPOSE: To set forth the protocol necessary for the immediate or timely return of the patient to the operating room when an emergency arises.

POLICY STATEMENT:

It is the policy of the Ambulatory Surgical Center (ASC) at LBJ to have a protocol for the immediate or timely return of a patient to the operating room when an emergency arises.

POLICY ELABORATIONS:

I. DEFINITIONS:

WORKFORCE: The employees, medical staff, trainees, contractors, volunteers, and vendors of the ASC at LBJ.

II. GENERAL PROCEDURES:

A. If a Workforce member is concerned about a patient's condition in the recovery area, the Workforce member will immediately:

1. Inform their supervisor;
2. Inform the anesthesiologist caring for the patient; and
3. Contact the patient's attending physician.

The supervisor or designee will:

Contact the Operating Room (OR) Charge Nurse;

The OR Charge Nurse will:

1. Consult with the Recovery Room Charge Nurse, the patient's attending physician, and the patient's anesthesiologist to determine if a return to the operating room is necessary;

2. If necessary, coordinate the immediate or timely return of the patient to the OR;

B. Following the return of the patient to the OR, the OR Charge Nurse will notify the ASC Administrator and Medical Director and submit an incident report in the electronic incident reporting system (eIRS) regarding the patient's return to the OR.

REFERENCES/BIBLIOGRAPHY:

AAAHC Version ~~43~~44

OFFICE OF PRIMARY RESPONSIBILITY:

Ambulatory Surgical Center at LBJ

REVIEW/REVISION HISTORY:

Effective Date	Version # (If Applicable)	Review/ Revision Date (Indicate Reviewed or Revised)	Approved by:
09/16/2016	1.0		The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/14/2019	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/13/2020	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/25/2021	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/17/2022	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/16/2023	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/22/2024	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Revised / Approved 02/20/2025	The Ambulatory Surgical Center (ASC) at LBJ Governing Body

TITLE: **MANAGEMENT AND ACCOUNTABILITY OF CONTROLLED SUBSTANCES**

PURPOSE: To establish guidelines for the storage, security, accountability, and handling of Controlled Substances in the Ambulatory Surgical Center (ASC) at LBJ.

POLICY STATEMENT:

The Ambulatory Surgical Center (ASC) at LBJ is committed to maintaining a safe environment for its patients and the community by enforcing the rules and regulations governing Controlled Substance accountability. Controlled Substance accountability shall be promoted in order to create an environment that prohibits substance abuse and diversion, which ultimately affects the safety of our patients and healthcare professionals. All healthcare disciplines shall work diligently and collaboratively to maintain strict adherence to rules and regulations governing Controlled Substance accountability.

POLICY ELABORATIONS:

I. DEFINITIONS:

A. **AUTHORIZED PERSONNEL**: Any licensed healthcare practitioner or other appropriately credentialed provider with access to Controlled Substances.

B. **AUTOMATED DISPENSING CABINET (ADC):** A mechanical system or device that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information (e.g. Pyxis®).

C. **CONTROLLED SUBSTANCE**: A substance, including a drug, an adulterant, and a dilutant, are listed in Schedules I through V or Penalty Group 1, 1-A, 2, 2- A, 3, or 4 (as more thoroughly described in Chapter 481 of the Texas Health and Safety Code) or as deemed by Harris Health.~~Medications classified as Schedule II, III, IV, or V and any unscheduled medications requiring additional controls as regulated by the Texas State Board of Pharmacy (TSBP), Drug Enforcement Agency (DEA), Texas Department of Public Safety, and/or Texas Department of Health.~~

D. **DISCREPANCY**: A situation resulting when the 'expected count' and the 'actual count' of a Controlled Substance are not identical. A discrepancy may be identified during a manual inventory, medication removal, or medical refill process.

E. ~~**DIVERSION:**~~ **DRUG DIVERSION:**: Knowingly taking without permission for one's use or benefit a Controlled Substance that an individual has access to by virtue of their profession or employment OR deliberately diverting to the unlawful use or benefit of another person a Controlled Substance that the individual has access to by virtue of the individual's profession or employment.

F. Examples of drug diversion include, but are not limited to, the following:

1. Pilfering/medication theft;

2. Using or taking possession of a medication without a valid order or prescription;

3. Forging or inappropriately modifying a prescription; or

~~E.~~ 4. Using or taking possession of medication waste, i.e., leftover medication~~The illegal delivery, possession, and/or theft of prescriptions, medications; obtaining prescription medications fraudulently; the unauthorized dispensing of prescription medications.~~

~~F.~~G. **PHARMACIST-IN-CHARGE (PIC):** The pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

G. **QUALIFIED LICENSED PRACTITIONER (QLP):** Any individual permitted by law and by Harris Health to provide care and services, without relevant direction or supervision, within the scope of the individual's license and consistent with individually granted clinical privileges.

H. **WORKFORCE**: Employees (permanent or temporary), Harris Health Board of Trustees, volunteers, trainees, medical staff, and other persons whose conduct, in the performance of work for Harris Health, is under the direct control of Harris Health, whether or not they are paid by Harris Health.

Formatted: Font: 14 pt
Formatted: Font: 14 pt
Formatted: Font: Italic
Formatted: Font: 14 pt
Formatted: Indent: First line: 0.5", No bullets or numbering
Formatted: Font: 14 pt, Not Italic

II. DEA REGISTRATION:

The Chief Pharmacy Officer (CPO) overseeing Department of Pharmacy (DOP) Operations shall maintain current registration of Harris Health pharmacies with the DEA for all necessary activities and will be responsible for all documentation.

III. STORAGE/SECURITY:

A. Only Authorized Personnel shall have access to the ASC's Controlled Substances.

B. Controlled Substances located in patient care areas will be stored in an ADC station.

C. Controlled Substances shall be stored according to the manufacturer's guidelines, in the original container, or an approved pre-packaged container in compliance with regulatory (DEA/TSBP/DPS) and accreditation agencies.

IV. MANAGEMENT OF CONROLLED SUBSTANCES

A. Harris Health Organization Responsibilities

1. An interdisciplinary Controlled Substances Oversight Committee (CSOC) is established to define, support, guide, and oversee the comprehensive CS diversion monitoring and prevention program.
2. CS data is generated and analyzed
3. The results of CS analysis are shared with the interdisciplinary CSOC to provide oversight to the comprehensive controlled substance diversion prevention program
4. Potential diversion cases shall be investigated as outlined in section VII of this policy
5. Drug diversion response in the organization includes but is not limited to:

    a. Assessment of harm to patients,
    b. Consultation with public health officials when tampering with injectable medication is suspected, and

c. Prompt reporting to state and federal enforcement agencies.

B. Pharmacy Responsibilities

1. The Pharmacist in Charge (PIC) is responsible for ensuring adequate procedures are in place for handling controlled substances in their areas (Refer to Harris Health Department of Pharmacy Procedure 3.80 Pharmacy Controlled Substances).
2. Physical Security of the Pharmacy

   a. Entry into the pharmacy shall be monitored via electronic access for all doors.
   b. Camera surveillance will be utilized.
   c. Pharmacy doors are badge-access yet still have lock with key. When applicable, keys to the main pharmacy or medication storage areas shall be clearly stamped with instructions to not duplicate and distribution shall be strictly limited to only essential personnel.

C. Surgical and Procedural Areas

1. CS are secured in the operating room, procedural areas, and anesthesia work areas during and between surgical cases.
2. Syringes prepared from multi-dose vials are labeled and kept under the control of the person preparing the syringes until administered.
3. CS dispensed for a surgical case are reconciled by Pharmacy against the products documented as administered or returned to the pharmacy.

D. Provider Orders/Prescribing

1. CS shall only be ordered/prescribed by licensed providers with DEA authorization.
2. Electronic systems shall be used to order/prescribe and communicate CS orders.
3. If written prescriptions are used, only authorized watermark prescription paper will be used.
4. All verbal orders require authorized prescriber signature.

E. Care Units Responsibilities

1. Only portless tubing shall be used for intravenous administration of CS.
2. ADC shall be used when available for storage/removal of CS upon a valid order.

   a. Medications shall be administered to the patient, returned to stock, or wasted within thirty (30) minutes upon removal.
   Exception: Medications removed in procedural areas shall be removed no more than thirty (30) minutes prior to procedure and returned or wasted immediately after the procedure.
   b. Administration of the medication shall be documented on the appropriate location on the electronic health record.
   c. Wastes and returns to stock shall be documented on the ADC or flowsheet as appropriate.

3. Returning/wasting of CS

   a. All CS medications returned or wasted shall be witnessed by two (2) licensed professionals (Registered Nurse, Licensed Vocational Nurse, Pharmacist, or Physician).
   b. Documentation of the wastage shall be completed at the time the controlled substance is actually wasted.
   ~~c. In non-ADC areas, administration and waste shall be documented and reconciled on the MCSAR.~~
   ~~d.~~c. Standard operating procedures for wasting common controlled substance dosage forms are outlined in Appendix A of this policy.

4. Inventory

   a. Medications shall be inventoried (count verified) during each transaction when CS are removed or added from the cabinet;
   b. Two (2) licensed staff members shall inventory CS once a week (each Wednesday);
   c. The PIC or designee shall monitor the weekly shift counts and notify

the Nurse Manager/Program Manager if the counts are not being completed each week; and

d. The PIC or designee shall notify the respective Director of Nursing if a unit/area fails to complete their weekly controlled substance inventory count timely.

e. The PIC or designee, in consultation with the Chief Nurse Executive (CNE) and CPO, shall jointly discuss and change the frequency of the inventory count in order to consistently comply with the law regulating controlled substance.

V. RECORD KEEPING:

All controlled substance records shall be kept in accordance with the Texas State Board of Pharmacy, Federal law, and Harris Health's Record Control Policy No. 3000.0.

VI. DISCREPANCY MONITORING:

A. Auditing/Report generation:

1. Routine auditing of CS shall occur on a proactive and retroactive basis using available audit tools and best practices.
2. The Patient Care Area or DOP personnel may also perform random audits of controlled substance administration records for discrepancies.

B. The organization shall utilize reports available in the ADC as well as manual audits as necessary to monitor for diversion and identify discrepancies

C. CS count discrepancies generated at the ADC shall be resolved before the end of the shift.

D. For CS count discrepancies generated at the ADC, the PIC or designee shall:

1. Review all CS discrepancies on a daily basis for validity and timeliness of

resolutions;

2. Forward pertinent CS discrepancies (i.e.: discrepancy with questionable resolution or not resolved within twenty-four (24) hours of its occurrence) to the Nurse Manager for review and response; and
3. Forward all pertinent discrepancy documentation to the Nurse Manager upon request.

E. Upon review of available information departmental leadership will be engaged to assist with classifying the identified discrepancies as one of the following:

1. **Resolved Discrepancy:** Discrepancy in which the explanation provided in a timely manner is plausible and adequate to account for the variation.
2. **Unresolved Discrepancy:** Discrepancy in which there is no plausible or adequate explanation to account for the discrepancy or where adequate response was not given within 72 hours of notification of the discrepancy.
3. **Suspected Diversion:** Discrepancy is surmised to be due to diversion without evidence/proof supporting diversion.
4. **Known Diversion/Theft:** Evidence suggests that the discrepancy is known to be due to diversion.

F. Resolution of individual unresolved discrepancies:

1. Notification of discrepancy is sent to the individuals involved, their immediate supervisor/manager, director, and the PIC or designee.
2. Discrepancies must be resolved within 48 hours from notification.
3. If no response is received within 48 hours from initial notification, the request shall be escalated to the Administrator for the ASC and LBJ (Administrator) .
4. Another 24 hours shall then be granted for resolution (total 72 hours from initial notification).
5. If an advanced practice provider, physician, medical student, or medical resident is involved in discrepancy or diversion, the appropriate medical staff leadership including chief of staff, Chief Medicine Officer (CMO), and Program Director will be notified for timely resolution.
6. Unless extenuating circumstances with a resolution plan are authorized by the Administrator, discrepancies that are not resolved within the allotted 72 hours shall be classified as a loss for reporting purposes as outlined in Section VII and in Appendix B of this policy.

G. Resolved discrepancies shall also be analyzed for patterns with individual users or units to determine if coaching is needed on processes.

VII. DISCREPANCY MONITORING

A. Auditing/Report generation:

1. Routine auditing of CS shall occur on a proactive and retroactive basis using available audit tools and best practices.
2. The Patient Care Area or DOP personnel may also perform random audits of controlled substance administration records for discrepancies.

B. The organization shall utilize reports available in the ADC as well as manual audits as necessary to monitor for diversion and identify discrepancies

C. CS count discrepancies generated at the ADC shall be resolved before the end of the shift.

D. For CS count discrepancies generated at the ADC, the PIC or designee shall:

1. Review all CS discrepancies on a daily basis for validity and timeliness of resolutions;
2. Forward pertinent CS discrepancies (i.e.: discrepancy with questionable resolution or not resolved within twenty-four (24) hours of its occurrence) to the Nurse Manager for review and response; and
3. Forward all pertinent discrepancy documentation to the Nurse Manager upon request.

E. Upon review of available information departmental leadership will be engaged to assist with classifying the identified discrepancies as one of the following:

1. **Resolved Discrepancy:** Discrepancy in which the explanation provided in a timely manner is plausible and adequate to account for the variation.
2. **Unresolved Discrepancy:** Discrepancy in which there is no plausible or adequate explanation to account for the discrepancy or where adequate response was not given within 72 hours of notification of the discrepancy.

3. **Suspected Diversion:** Discrepancy is surmised to be due to diversion without evidence/proof supporting diversion.
4. **Known Diversion/Theft:** Evidence suggests that the discrepancy is known to be due to diversion.

F. Resolution of individual unresolved discrepancies, in the absence of suspicion of diversion:~~:~~

1. Notification of discrepancy is sent to the individuals involved, their immediate supervisor/manager, director, and the PIC or designee.
2. Discrepancies must be resolved within 48 hours from notification.
3. If no response is received within 48 hours from initial notification, the request shall be escalated to the Administrator.
4. Another 24 hours shall then be granted for resolution (total 72 hours from initial notification).
5. If an advanced practice provider, physician, medical student, or medical resident is involved in discrepancy or diversion, the appropriate medical staff leadership including chief of staff, Chief Medicine Officer (CMO), and Program Director will be notified for timely resolution.
6. Unless extenuating circumstances with a resolution plan are authorized by the Administrator, discrepancies that are not resolved within the allotted 72 hours shall be classified as a loss for reporting purposes as outlined in Section VII and in Appendix B of this policy.
7. Resolved discrepancies shall also be analyzed for patterns with individual users or units to determine if coaching is needed on processes.

VIII. SUSPECTED/KNOWN DIVERSION

Suspected theft or significant losses of CS shall be reported by the PIC of the affected pavilion or designee to the Harris Health System CS Diversion Response Team for action and investigation in accordance with established procedure (Appendix B).

IX. DRUG DIVERSION RESPONSE TEAM

A. The Drug Diversion Response Team (DDRT) is a team formed by the CSOC and acts at the direction of the CSOC. The DDRT manages the investigation of

all reports of known or suspected Drug Diversion under the direction of the Risk Management team lead (Diversion Manager).

B. The DDRT is a multidisciplinary team made up of the following disciplines:

1. Nursing;
2. Pharmacy;
3. Risk Management;
4. Human Resources(HR);
5. Corporate Compliance;
6. Administration; and
7. Security

REFERENCES/BIBLIOGRAPHY:

Texas State Board of Pharmacy(TSBP)

Drug Enforcement Agency (DEA)

Texas Department of Public Safety and Texas Department of Health

84 FR 5816 (40 CFR 261-273)

AAAHC Version 4~~3~~

APPENDICES:

Appendix	Title
Appendix A	Standard Operating Procedure for Wasting Common Controlled Substance Dosage Forms
Appendix B	Guidelines for Determination of Significant Loss

~~Appendix A: Standard Operating Procedure for Wasting Common Controlled Substance Dosage Forms~~

~~Appendix B: Guidelines for Determination of Significant Loss~~

FORMS:

Harris Health Form 284588 Unit Narcotic Reconciliation Form

Harris Health Form 282139 Perpetual Inventory Record for Controlled Substances

Harris Health Form 282158 Multi-Purpose Controlled Substance Administration Record (MCSAR)

OFFICE OF PRIMARY RESPONSIBILITY:

Harris Health System Department of Pharmacy Services

Harris Health System Department of Nursing Services

REVIEW/REVISION HISTORY:

Effective Date	Version # (If Applicable)	Review/ Revision Date (Indicate Reviewed or Revised)	Approved by:
9/16/16	1.0	9/16/16	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 3/29/18	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/14/2019	The Ambulatory Surgical Center (ASC) at LBJ Governing Body

		Reviewed / Approved 02/13/2020	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/25/2021	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/17/2022	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/16/2023	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Reviewed / Approved 02/22/2024	The Ambulatory Surgical Center (ASC) at LBJ Governing Body
		Revised / Approved 02/20/2025	The Ambulatory Surgical Center (ASC) at LBJ Governing Body

APPENDIX A:

STANDARD OPERATING PROCEDURE FOR WASTING COMMON CONTROLLED SUBSTANCE (CS) DOSAGE FORMS

General Considerations:

- ***** Do not flush or discard medications in the sink (a.k.a. "sewering")*****
- CS medications shall be disposed of in approved non-retrievable containers. If an area begins to accept CS waste, please email Hazardous Materials (HazardousMaterials@harrishealth.org) to set up an approved non-retreivable container in the area for wasting CS.
- Waste shall require authorized WITNESS for verification
- Waste documentation shall include drug name, wasted amount, and witness name
- **Intact containers** of CS medications (i.e., unopened/ unused due to patient refusal, order cancellation, etc.) shall be returned via appropriate return processing
- **Open or PARTIALLY** used CS medication (i.e., seal is broken) shall be wasted based on the dosage form and the guideline below
- Please note that this list is not exhaustive. For questions regarding controlled substances, contact Pharmacy.

DOSAGE FORM	DISPOSAL INSTRUCTIONS
Proper disposal of a **transdermal** patch	• Fold patch so sticky sides are together, being careful not to touch the medication on the patch • Dispose patch in the patch slot of the Cactus sink, using the attached tool to push it through the slot. • Do NOT flush the patch cover
Proper disposal of oral **capsules**	• Drop capsule into the pill maze of the Cactus sink
Proper disposal of oral **tablets**	• Drop tablets into the pill maze of the Cactus sink
Proper disposal of oral **solution**	• Dispose of oral solution into the liquid receptacle of the Cactus sink
Proper disposal of **sublingual film**	• Discard film in the approved non-retrievable container
Proper disposal of **rectal gel**	• **Before** discarding the applicator, dispose any remaining rectal gel (applicator tip is pointed over the approved non-retrievable container, the plunger pulled back then gently depressed until it stops to force gel from the applicator tip into the container) • Dispose the empty applicator in the appropriate biohazard bin
Proper disposal of **injectable medications or infusions**	• Drain the remaining amount into the liquid receptacle of the Cactus sink • Dispose broken vial and/or syringe in the red sharps container • Dispose of empty containers in the regular trash

APPENDIX B
GUIDELINES FOR DETERMINATION OF SIGNIFICANT LOSS

Federal regulations require that registrants notify the DEA Field Division Office in their area, in writing, of the theft or significant loss of any CS within one business day of discovery of such loss or theft. The theft or significant loss of any controlled substance by a pharmacy shall also be reported in writing to the Texas State Board of Pharmacy immediately on discovery of such theft or loss. A pharmacy shall be in compliance with this subsection by submitting to the board a copy of the Drug Enforcement Administration (DEA) report of theft or loss of controlled substances, DEA Form 106, or by submitting a list of all controlled substances stolen or lost.

At Harris Health System, the following definitions shall apply for determining when a loss is reportable:

a. **SIGNIFICANT LOSS**: Any discrepancy that is not resolved within the time defined in Harris Health System policy after investigation shall be considered a significant loss and reported to the DEA and the Texas State Board of Pharmacy.

b. **THEFT**: any loss due to confirmed diversion by any individual while the controlled substance is in the control of Harris Health. Any loss due to confirmed diversion, regardless of the amount, shall be reported to the DEA and the Texas State Board of Pharmacy.

The Pharmacist in Charge (PIC) of the area where the theft or significant loss occurred shall complete and submit the DEA Form 106 to the Field Division office in their area and to the Texas State Board of Pharmacy.

BOARD OF TRUSTEES

Ambulatory Surgical Center at LBJ Governing Body

HARRISHEALTH

Thursday, February 19, 2026

Consideration of Approval of Reviewed Policies and Procedures with No Recommended Changes for the Ambulatory Surgical Center

---

As part of the regulatory requirements of the Ambulatory Surgical Center, the Governing Body is to review and approve policies for the ASC annually.

Listed below is a summary of the reviewed policies with no changes.

- Policies ASC-P-1000-1002
- Policies ASC-P-1006-1010
- Policies ASC-P-2000-2023
- Policies ASC-P-3000-3005
- Policies ASC-P-4000-4001
- Policies ASC-P-4003-4004
- Policies ASC-P-4006-4013
- Policies ASC-P-5000-5001
- Policy ASC-P-5003
- Policies ASC-P-5005-5007
- Policies ASC-P-6000-6002
- Policies ASC-P-6004-6013
- Policies ASC-P-6017-6018
- Patient Safety Plan