SIERRA VIEW
MEDICAL CENTER

SIERRA VIEW LOCAL HEALTH CARE DISTRICT
BOARD OF DIRECTORS MEETING
465 West Putnam Avenue, Porterville, CA – Board Room

AGENDA
October 24, 2023

OPEN SESSION (5:00 PM)

The Board of Directors will call the meeting to order at 5:00 P.M. at which time the Board of Directors will undertake procedural items on the agenda. At 5:05 P.M. the Board will move to Closed Session regarding the items listed under Closed Session. The public meeting will reconvene in person at 5:30 P.M. In person attendance by the public during the open session(s) of this meeting is allowed in accordance with the Ralph M. Brown Act, Government Code Sections 54950 et seq.

Call to Order

I. Approval of Agendas
Recommended Action: Approve/Disapprove the Agenda as Presented/Amended

The Board Chairman may limit each presentation so that the matter may be concluded in the time allotted. Upon request of any Board member to extend the time for a matter, either a Board vote will be taken as to whether to extend the time allotted or the chair may extend the time on his own motion without a vote.

II. Adjourn Open Session and go into Closed Session

CLOSED SESSION (5:01 PM)

As provided in the Ralph M. Brown Act, Government Code Sections 54950 et seq., the Board of Directors may meet in closed session with members of the staff, district employees and its attorneys. These sessions are not open to the public and may not be attended by members of the public. The matters the Board will meet on in closed session are identified on the agenda or are those matters appropriately identified in open session as requiring immediate attention and arising after the posting of the agenda. Any public reports of action taken in the closed session will be made in accordance with Gov. Code Section 54957.1

III. Closed Session Business

A. Pursuant to Evidence Code Sections 1156 and 1157.7; Health and Safety Code Section 32106(b): Chief of Staff Report

B. Pursuant to Evidence Code Sections 1156 and 1157.7; Health and Safety Code Section 32106(b):

1. Evaluation – Quality of Care/Peer Review/Credentials

2. Quality Division Update –Quality Report

C. Pursuant to Gov. Code Section 54962; Health and Safety Code Section 32106(b); Cal. Civ. Code § 3426.1(d): Discussion Regarding Trade Secrets (1 Item) Estimated Date of Disclosure – January 2024

D. Pursuant to Gov. Code Section 54962; Health and Safety Code Section 32106(b); Cal. Civ. Code § 3426.1(d): Discussion Regarding Trade Secrets (1 Item) Estimated Date of Disclosure – March 2025

E. Pursuant to Gov. Code Section 54962; Health and Safety Code Section 32106(b): Discussion Regarding Trade Secrets Pertaining to Service and Strategic Planning

F. Pursuant to Gov. Code Section 54956.9(d)(2): Conference with Legal Counsel about recent work product (b)(1) and (b)(3)(F): significant exposure to litigation; privileged communication (1 Item)

To the extent items on the Closed Session Agenda are not completed prior to the scheduled time for the Open Session to begin, the items will be deferred to the conclusion of the Open Session Agenda.

IV. Adjourn Closed Session and go into Open Session

OPEN SESSION (5:30 PM)

V. Closed Session Action Taken

Pursuant to Gov. Code Section 54957.1; Action(s) to be taken Pursuant to Closed Session Discussion

A. Chief of Staff Report
Recommended Action: Information only; no action taken

B. Quality Review

1. Evaluation – Quality of Care/Peer Review/Credentials
   Recommended Action: Approve/Disapprove Report as Given

2. Quality Division Update –Quality Report
   Recommended Action: Approve/Disapprove Report as Given

C. Discussion Regarding Trade Secret
Recommended Action: Approve/Disapprove Report as Given

D. Discussion Regarding Trade Secret
Recommended Action: Information only; no action taken

E. Discussion Regarding Trade Secret and Strategic Planning
Recommended Action: Information only; no action taken

F. Conference with Legal Counsel
Recommended Action: Information only; no action taken

VI. Public Comments

Pursuant to Gov. Code Section 54954.3 - NOTICE TO THE PUBLIC - At this time, members of the public may comment on any item not appearing on the agenda. Under state law, matters presented under this item cannot be discussed or acted upon by the Board at this time. For items appearing on the agenda, the public may make comments at this time or present such comments when the item is called. This is the time for the public to make a request to move any item on the consent agenda to the regular agenda. Any person addressing the Board will be limited to a maximum of three (3) minutes so that all interested parties have an opportunity to speak with a total of thirty (30) minutes allotted for th e Public Comment period. Please state your name and address for the record prior to making your comment. Written comments submitted to the Board prior to the Meeting will distributed to the Board at this time, but will not be read by the Board secretary during the public comment period.

VII. Consent Agenda

Recommended Action: Approve Consent Agenda as presented

Background information has been provided to the Board on all matters listed under the Consent Agenda, covering Medical Staff and Hospital policies, and these items are considered to be routine by the Board. All items under the Consent Agenda

covering Medical Staff and Hospital policies are normally approved by one motion. If discussion is requested by any Board member(s) or any member of the public on any item addressed during public comment, then that item may be removed from the Consent Agenda and moved to the Business Agenda for separate action by the Board.

VIII. Approval of Minutes

A. **September 26, 2023 Minutes of the Regular Meeting of the Board of Directors**
Recommended Action: Approve/Disapprove September 26, 2023 Minutes of the Regular Meeting of the Board of Directors

IX. CEO Report

X. Business Items

A. **FY2023 Audited Financials Report**
Recommended Action: Approve/Disapprove Report as Given

B. **September 2023 Financials**
Recommended Action: Approve/Disapprove Report as Given

XI. Announcements:

A. Regular Board of Directors Meeting – November 28, 2023 at 5:00 p.m.

XII. Adjournment

PUBLIC NOTICE

Any person with a disability may request the agenda be made available in an appropriate alternative format. A request for a disability-related modification or accommodation may be made by a person with a disability who requires a modification or accommodation in order to participate in the public meeting to Melissa Mitchell, VP of Quality and Regulatory Affairs, Sierra View Medical Center, at (559) 788-6047, Monday – Friday between 8:00 a.m. – 4:30 p.m. Such request must be made at least 48 hours prior to the meeting.

PUBLIC NOTICE ABOUT COPIES

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Senior Leadership Team	10/24/2023
Board of Director's Approval	
Bindusagar Reddy, MD, Chairman	10/24/2023

SIERRA VIEW MEDICAL CENTER
CONSENT AGENDA
October 24, 2023
BOARD OF DIRECTOR'S APPROVAL

The following Polices/Procedures/Protocols/Plans have been reviewed by Senior Leadership Team and are being submitted to the Board of Director's for approval:

	Pages	Action
Policies:		Approve ↓
1. Catering Services	1-2	
Forms:		
1. 013053 Notice of Privacy Practices (SPANISH)	3-9	
2. 025521 Cardiac Clearance	10	
3. 025522 Joint PT Rx 091823	11	
4. 025523 Orthotics Order Form 091823	12	
5. 025525 Ortho Encounter Form 091823	13-14	
6. 025527 Referral Form 091823	15	
7. 013049 Notice of Privacy Practices (ENGLISH)	16-22	

SUBJECT: **CATERING SERVICES**	SECTION: **Page 1 of 2**

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

PURPOSE:

Catering services are provided for meetings and special events at Sierra View Medical Center (SVMC).

POLICY:

1. Catering will be provided in support of the Board of Director's meetings, administration and special events approved by administration *(town hall, benefits fair, etc.)*. Physicians may be provided a pre-plated meal when attending meetings during their meal period. A banquet style setup may be provided for meetings such as General Medical Staff Meeting, Medical Executive Committee, Tumor Board, Cancer Support Group, Weekly Physician's Mingler and physician's office staff training.

2. It is the requesting party's responsibility to reserve the conference room for their catered event. SVMC conference rooms may be reserved through Microsoft Outlook.

3. Catering expenses for events are tracked utilizing the catering FormStack request form.

4. Catering requests will be received no less than 7 days prior to the event. Requests for events with attendance of 50 or more will be received 30 days in advance. Short notice requests may be directed to the Café for meal compensation.

5. Linen will only be utilized for hospital approved events. Linen will not be used for department planned events *(Christmas parties, pot lucks, birthday parties, etc.)*.

6. Catering requests from outside vendors or community groups for hospital events must be approved by administration.

AFFECTED PERSONNEL/AREAS: *ALL DEPARTMENTS*

PROCEDURE:

1. Catered events will be requested and processed using the catering FormStack on SVMC's intranet. The catering request form is located on the front page of the SVMC intranet, under "Service Requests".

2. If a change occurs (i.e., meeting cancelled, the number of individuals attending changes, room changes, etc.), it is the responsibility of the requesting party to notify the Food and Nutrition Services (FNS) Department immediately at extension 4758.

3. Catering menus will be determined by the FNS Department.

4. If the catering event concludes early, FNS will be notified at extension 4758 for cleanup.

5. To prevent food poisoning incidents, loss of catering equipment, and to meet health department and federal government food guidelines for hazard analysis critical control points (HACCP), left-over food, supplies and equipment will **not** be removed from the catering location.

REFERENCES:

- Human and Health Service Agency, Tulare County Environmental Health Department. Retrieved from https://tularecountyeh.org/eh/.

- Hazard Analysis Critical Control Point (HACCP). Retrieved from https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/hazard-analysis-critical-control-point-haccp.

SIERRA VIEW MEDICAL CENTER
AVISO DE PRÁCTICAS DE PRIVACIDAD

AVISO DE PRÁCTICAS DE PRIVACIDAD

Efectivo el 1 de octubre de 2023

Este Aviso de Privacidad describe las prácticas de todos los empleados, el Personal y otro Personal de Sierra View Medical Center (SVMC), cualquier profesional de la salud autorizado para ingresar información en su cuadro de SVMC, todos los departamentos, unidades e instalaciones de SVMC, cualquier miembro de un grupo de voluntarios a quien le permitimos que le ayude mientras usted usa los servicios de SVMC y todos los médicos, residentes, estudiantes de medicina, estudiantes y profesionales de la salud aliados que ofrecen atención en cualquier instalación de SVMC.

Su información y registros de tratamiento médico y de salud mental son personales y privados. Sierra View Medical Center se compromete a proteger su información de salud. La información médica y de salud mental que creamos y mantenemos se conoce como Información protegida de salud/Información protegida de salud electrónica o PHI/ePHI. Las leyes federales y estatales nos exigen que protejamos la privacidad de su información médica y de salud mental y que obtengamos una autorización firmada por usted para ciertas divulgaciones.

La ley nos exige que le brindemos este Aviso de nuestros deberes legales y prácticas de privacidad con respecto a su información médica y de salud mental. Este Aviso explica cómo podemos legalmente usar y divulgar su información protegida de salud y sus derechos con respecto a la privacidad de su información protegida de salud. Estamos obligados a seguir todos los términos de este aviso. Nos reservamos el derecho de cambiar las disposiciones de este Aviso y hacerlo vigente para toda la información protegida de salud que mantenemos.

Las prácticas de privacidad de la información descritas en este Aviso serán seguidas por:

- Cualquier profesional de la salud que lo trate en cualquiera de nuestras ubicaciones
- Todas las instalaciones, departamentos y unidades, incluidos hospitales, centros quirúrgicos, clínicas y otros afiliados
- Todos los miembros de la fuerza laboral, tales como empleados, personal médico, aprendices, estudiantes, voluntarios y otras personas bajo nuestro control directo, independientemente de que les paguemos o no.
- Otros proveedores de atención médica que aceptaron acatar este Aviso de prácticas de privacidad

Si tiene alguna pregunta y/o desea información adicional, puede comuníquese con el Oficial de Cumplimiento/Privacidad al (559)791-3838 o con la Línea Directa de Cumplinmiento al (559)791-4777.

Cómo podemos utilizar y divulgar su información protegida de salud

Las siguientes categorías describen diferentes formas en que utilizamos y divulgamos su información protegida de salud. Para cada categoría, explicaremos lo que queremos decir e intentaremos dar algunos ejemplos. No se enumerarán todos los usos o divulgaciones en una categoría. Sin embargo, todas las formas en que se nos permite utilizar y divulgar su información protegida de salud recaerán en una de las categorías. Describiremos por separado las formas en que utilizamos y divulgamos información sobre el VIH/SIDA y sobre el abuso de sustancias y/o alcohol más adelante en este Aviso.

1. Tratamiento

Podemos utilizar y divulgar su información protegida de salud para proporcionar, coordinar o administrar su atención médica y cualquier servicio relacionado. También podemos divulgar su información de salud a otros proveedores que lo pueden tratar o involucrarse en su cuidado.

2. Pago

Podemos utilizar o divulgar su información protegida de salud para obtener el pago de los servicios de atención médica que se le brindan. Por ejemplo, podemos incluir información con una factura a Medi-Cal o Medicare que lo identifique, a su diagnóstico y a los servicios prestados para recibir el pago.

3. Operaciones de atención médica

Podemos utilizar y divulgar su información protegida de salud para respaldar las actividades comerciales de Sierra View Medical Center. Por ejemplo, podemos usar su información protegida de salud para revisar y evaluar nuestro tratamiento y servicios o para mejorar la atención y los servicios que ofrecemos. Además, podemos divulgar su información de salud con otro personal o socios comerciales, que realizan servicios de facturación, consultoría, auditoría, investigación y otros servicios para Sierra View Medical Center.

4. Directorio del hospital

Podemos incluir cierta información limitada sobre usted en el directorio del hospital mientras sea paciente en el hospital. Esta información puede incluir su nombre, ubicación en el hospital, su condición general (por ejemplo, buena, regular, etc.) y su afiliación religiosa. A menos que exista una solicitud específica por escrito de usted para lo contrario, esta información de directorio, excepto su afiliación religiosa, también se puede divulgar a las personas que pregunten por usted por su nombre. Su afiliación religiosa puede ser dada a un miembro del clero, como un sacerdote o rabino, incluso si no preguntan por usted por su nombre. Esta información se divulga para que su familia, amigos y clérigos puedan visitarlo en el hospital y, en general, saber cómo está.

5. Actividades de recaudación de fondos

Podemos utilizar su información o divulgar dicha información a una fundación relacionada con el hospital para comunicarnos con usted en un esfuerzo por recaudar dinero para el hospital y sus operaciones. Usted tiene el derecho de excluirse de recibir comunicaciones de recaudación de fondos. Si recibe una comunicación de recaudación de fondos, esta le dirá cómo excluirse.

6. Comercialización y venta

La mayoría de los usos y divulgaciones de información médica, incluidos los usos de las fotografías de los pacientes con fines de comercialización y las divulgaciones que constituyen una venta de información médica, requieren su autorización.

7. Requerido por la ley

Utilizaremos y divulgaremos su información protegida de salud cuando así lo requiera la ley federal, estatal o local.

8. Actividades de supervisión de la salud

Podemos divulgar su información protegida de salud a agencias federales o estatales que auditan, investigan e inspeccionan los programas de beneficios de salud del gobierno.

9. Actividades de salud pública

Podemos utilizar y divulgar su información protegida de salud a autoridades de salud pública o agencias gubernamentales para informar ciertas enfermedades, lesiones, afecciones y eventos según lo exija la ley. Por ejemplo, podemos divulgar su información médica a una agencia del gobierno local para ayudar a la agencia durante la investigación de un brote de enfermedad en el área.

10. Víctimas de abuso, abandono o violencia doméstica

Podemos divulgar su información protegida de salud a otras agencias gubernamentales para reportar sospechas de abuso, negligencia o violencia doméstica. Solo divulgaremos esta información si usted está de acuerdo, si la ley así lo exige o si es necesario para proteger a alguien de daños graves.

11. Demandas y acciones legales

Podemos divulgar su información médica protegida en respuesta a una orden judicial, citación u otro proceso legal, según lo permita la ley, para procedimientos legales.

12. Aplicación de la ley

Podemos divulgar su información protegida de salud a agentes del orden público, como la policía, el sheriff, al Servicio de Inmigración y Control de Aduanas (ICE) o al FBI, en respuesta a una orden de registro u orden judicial, para localizar o identificar a una persona desaparecida, un sospechoso o un fugitivo.
Además, podemos divulgar su información para denunciar un delito que ocurre en nuestras clínicas u oficinas o para informar sobre ciertos tipos de heridas, lesiones o muertes que pueden resultar de un delito.

13. Médicos forenses, examinadores médicos y directores de funerarias

Podemos divulgar su información protegida de salud a directores de funerarias, médicos forenses y examinadores médicos para identificar a una persona muerta, determinar qué causó la muerte u otros deberes oficiales.

14. Donación de órganos y tejidos

Podemos divulgar su información protegida de salud a organizaciones que se ocupan de las donaciones y trasplantes de órganos, ojos o tejidos.

15. Investigación

Podemos usar y divulgar su información protegida de salud para investigación, si es aprobada por una Junta de Revisión Institucional (IRB). Una IRB es un comité responsable de revisar la propuesta de investigación y establecer protocolos para garantizar la privacidad de su información protegida de salud.

16. Para detener una amenaza grave a la salud o la seguridad

Podemos utilizar o divulgar su información médica protegida si es necesario para disminuir la amenaza inminente de una amenaza grave para la salud o la seguridad.

17. Reclusos

Si usted es un recluso de una institución correccional, podemos divulgar su información protegida de salud a la institución correccional para proteger su salud y seguridad o para proteger la salud y seguridad de otros en la institución.

18. Actividad militar y seguridad nacional

Si es o fue miembro de las fuerzas armadas, podemos divulgar su información protegida de salud a las autoridades militares. También podemos compartir su información protegida de salud con funcionarios federales autorizados cuando sea necesario para la seguridad nacional, las actividades de inteligencia o la protección del presidente u otros funcionarios gubernamentales.

19. Programas gubernamentales para beneficios públicos

Podemos utilizar o divulgar su información protegida de salud para ayudarlo a calificar para los programas de beneficios del gobierno, tales como Medicare, Medi-Cal, Seguridad de Ingreso Suplementario u otros beneficios o servicios disponibles. También podemos comunicarnos con usted para informarle sobre posibles opciones de tratamiento o beneficios o servicios relacionados con la salud, previa autorización por escrito.

20. Compensación de los trabajadores

Utilizaremos y divulgaremos su información protegida de salud para la compensación de los trabajadores o programas similares que brinden beneficios por lesiones o enfermedades relacionadas con el trabajo.

21. Familia y amigos involucrados o que pagan por su cuidado

Podemos divulgar su información protegida de salud a un amigo, familiar o cualquier otra persona que usted identifique como implicada en su atención médica o en el pago de su atención. Por ejemplo, puede llevar a un amigo o familiar a su cita y tener a esa persona en la sala de examen mientras habla con un proveedor de atención médica. Puede informarnos verbalmente o por escrito si se opone a las divulgaciones a su familia y amigos.

22. Alivio de desastres

Podemos divulgar su información protegida de salud a entidades públicas o privadas en un desastre para proporcionar la atención médica necesaria o para ayudarlo a encontrar a miembros de su familia.

23. Recordatorios de citas

Podemos utilizar la información de contacto que nos proporcionó para recordarle sus próximas citas médicas con Sierra View Medical Center.

24. Registros de inmunización

Podemos divulgar la prueba de inmunización de su hijo a su escuela, si el estado u otra ley requieren que la escuela tenga dicha información antes de admitir a su hijo como estudiante. Obtendremos la autorización de los padres o tutores antes de hacerlo, aunque esto puede hacerse de manera informal.

Usos y divulgaciones de su información médica protegida que requieren su permiso

Obtendremos su permiso por escrito a través de una autorización para otros usos y divulgaciones de su información protegida de salud que no esté cubierta por este Aviso. Puede revocar la autorización por escrito en cualquier momento y dejaremos de divulgar información protegida de salud sobre usted por las razones indicadas en su autorización escrita. Cualquier divulgación hecha antes de la revocación no se ve afectada por la revocación. También estamos obligados a conservar nuestros registros de la atención que recibe de SVMC.

Usos y divulgaciones de información sobre VIH/SIDA

Podemos divulgar cualquier registro de salud pública relacionado con el VIH/SIDA que desarrollemos o adquiramos que contenga su información protegida de salud según lo dispuesto por ley para fines de salud pública u otras agencias de salud pública o investigadores médicos que lo corroboren cuando la información sea necesaria para llevar a cabo sus tareas de investigación, control o vigilancia de enfermedades.

Su médico que ordena una prueba de VIH en su nombre puede divulgar el resultado de su prueba de VIH a sus proveedores de atención médica para fines relacionados con su diagnóstico, atención o tratamiento.

Usos y divulgaciones de su información sobre abuso de sustancias y alcohol

La confidencialidad de sus registros de abuso de alcohol y drogas que mantenemos está protegida por la ley y los reglamentos federales. En general, no se nos permite divulgar a una persona externa su participación en el programa ni identificarlo como consumidor de alcohol o drogas, a menos que:

(1) Usted manifieste su consentimiento por escrito;

(2) La divulgación está permitida por una orden judicial; o

(3) La divulgación se realiza al personal médico en una emergencia médica o al personal calificado para investigación, auditoría o evaluación del programa.

Las leyes y normativas federales no protegen ninguna información sobre un delito cometido por usted ni en nuestro programa ni contra ninguna persona que trabaje para el programa ni sobre ninguna amenaza para cometer dicho delito.

Las leyes y reglamentos federales no protegen ninguna información sobre sospecha de abuso o negligencia infantil de ser reportada en virtud de la ley estatal a las autoridades estatales o locales apropiadas.

Sus derechos con respecto a la información protegida de salud sobre usted

1. Derecho a inspeccionar y copiar

Usted tiene derecho a inspeccionar y copiar su información protegida de salud en nuestro conjunto de registros designado, que incluye registros médicos y de facturación, siempre que mantengamos esa información. Usted tiene derecho a acceder a sus registros en cualquier formato en el que Sierra View Medical Center los mantenga y puede enviarlos a un tercero. Se debe presentar una solicitud por escrito y se puede cobrar una tarifa por los costos de copiado, envío por correo y cualquier otro material utilizado para cumplir con su solicitud. Podemos denegar su solicitud para inspeccionar y copiar sus registros. Si esto ocurre, le enviaremos una declaración por escrito con los motivos y le explicaremos su derecho, si corresponde, a que se revise la denegación.

2. Derecho a solicitar una enmienda

Tiene derecho a solicitar que modifiquemos su información protegida de salud si considera que es incompleta o inexacta. La solicitud debe ser por escrito y proporcionar los motivos que respaldan su solicitud, incluida la información incompleta o inexacta.

Podemos denegar su solicitud si no está por escrito o no incluye un motivo para respaldar la solicitud. También podemos denegar su solicitud si:

- La información es correcta y precisa.
- La información no fue creada por nosotros.
- La persona que lo creó ya no está disponible para realizar la enmienda.
- La información no es parte de los registros que se le permite inspeccionar y copiar.

Si denegamos su solicitud de enmienda, usted tiene derecho a presentar un anexo por escrito que no exceda de cinco (5) páginas. Puede solicitar por escrito que la adición escrita se agregue a sus registros médicos, junto con su solicitud original para cambiar su información médica y la denegación por escrito para realizar el cambio.

3. Derecho a un informe de divulgaciones

Usted tiene derecho a solicitar un "informe de divulgaciones", que es una lista de divulgaciones que realizamos de su información protegida de salud. La solicitud debe hacerse por escrito y solo puede incluir divulgaciones que ocurrieron entre la fecha de su solicitud y hasta seis años antes de esta fecha, pero no antes del 14 de abril de 2003. La lista no incluirá divulgaciones:

- Basadas en su autorización escrita;
- Para tratarlo o para recibir el pago de su tratamiento;
- Por ciertos motivos comerciales;
- Para miembros de la familia o amigos involucrados en su tratamiento o cuidado médico;
- A las cárceles, prisiones o la aplicación de la ley; o
- Por razones relacionadas con acciones legales.

Para los registros electrónicos de salud (EHR), el informe de las divulgaciones también incluiría las divulgaciones de su información protegida de salud realizadas para llevar a cabo el tratamiento, el pago y las operaciones de atención médica. Este requisito se limita a las divulgaciones dentro del período de tres (3) años anterior a su solicitud y después del 1 de enero de 2014.

Puede solicitar un informe gratuito de divulgaciones en un período de 12 meses, pero puede que le cobren por listas adicionales.

4. Derecho a solicitar restricciones

Tiene derecho a solicitar una restricción o limitación sobre cómo usamos o divulgamos su información protegida de salud para tratamiento, pago u operaciones de atención médica. Por ejemplo, puede pedirnos que limitemos la información que compartimos con alguien que está involucrado en su atención o en el pago de su atención. Por ejemplo, puede solicitar que limitemos las divulgaciones a su cónyuge. Podemos pedirle que nos entregue su solicitud por escrito. Si aceptamos su solicitud, no usaremos ni divulgaremos la información protegida de salud en violación de dicha restricción, excepto si creemos que esta información es necesaria para proporcionarle el tratamiento o cuidado médico necesario.

No estamos obligados a aceptar su solicitud, excepto que tiene derecho a restringir las divulgaciones a un plan de salud o a su socio comercial si usted o alguien en su nombre paga de su bolsillo en su totalidad por el artículo o servicio de atención médica, a menos que se nos exija por ley divulgar la información protegida de salud. Requerimos que el pago se realice en su totalidad en el momento de la solicitud de restricción. Si no se realiza el pago, la restricción será nula y se divulgará la información protegida de salud a su plan de salud para el pago. En algunos casos donde una restricción de divulgación no puede hacerse o involucra a otra parte, lo conversaremos con usted en detalle.

5. Derecho a solicitar comunicaciones confidenciales

Tiene derecho a solicitar cómo nos comunicamos con usted para preservar su privacidad. Por ejemplo, puede solicitar que lo llamemos solo a su número de trabajo o enviar un correo a una dirección especial. Su solicitud debe hacerse por escrito y debe especificar cómo o dónde debemos comunicarnos con usted. Atenderemos todas las solicitudes razonables.

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6. Derecho a revocar una autorización

Usted tiene derecho a retirar o revocar su autorización escrita para usar y divulgar su información protegida de salud en cualquier momento. Debe informarnos por escrito. Si retira su autorización por escrito, dejaremos de compartir su información protegida de salud. Sin embargo, no podemos recuperar ninguna información ya utilizada o compartida mientras la autorización era válida.

Sierra View Medical Center está obligada por ley a llevar un registro del tratamiento médico que recibe de la instalación, ya sea que nos dé o no un permiso por escrito para usarlo o compartirlo. Usted no tiene derecho a que se elimine información de su registro.

7. Derecho a una copia impresa de este aviso

Usted tiene derecho a recibir una copia en papel de este aviso cada vez que lo solicite, a menos que sea un recluso en la cárcel.

8. Aviso de incumplimiento

En el caso de una violación de su información protegida de salud no segura, Sierra View Medical Center le notificará las circunstancias de la violación.

9. Derecho a presentar una queja

Si cree que se han violado sus derechos de privacidad, puede presentar una queja ante el hospital o con el Secretario de Estado del Departamento de Salud y Servicios Humanos de Estados Unidos. Para presentar una queja con el hospital, comuníquese con el Oficial de Cumplimiento/Privacidad al (559) 791-3838, el Línea directa de cumplimiento al (559)791-4777, o por escrito a Sierra View Medical Center, C/O Oficial de Cumplimiento/Privacidad, 465 W. Putnam, Porterville, California 93257

No se tomarán represalias en su contra por presentar una queja.

Nuestras responsabilidades

Debemos seguir los términos de este Aviso mientras esté en vigencia. Nos reservamos el derecho de cambiar este Aviso y nuestras prácticas de privacidad en cualquier momento. Los cambios en nuestras prácticas de privacidad se aplicarán a cualquier información protegida de salud que ya tenemos y a la información protegida de salud que creamos o recibimos en el futuro. También publicaremos y pondremos disponible el nuevo Aviso en las ubicaciones de Sierra View Medical Center en las áreas de espera o en la recepción. El Aviso también estará disponible en el sitio web de Sierra View Medical Center en *http://www.sierra-view.com/NoticeofPrivacyPractices*.

Sierra View Hip and Knee Center

263 Pearson Dr. Suite 206, Porterville, CA 93257
Phone: (559) 788-6081
Fax: (559) 544-1004

Date: _____

Clearance is being requested for the following patient.

□ Medical □ Cardiac □ Renal □ Hematology □ Pulmonary □ Other _____

Patient Name: _____ DOB: _____

Scheduled surgery date: _____

Type of Surgery

Total Knee Replacement _____ Total Hip Replacement _____

Revision Knee Replacement _____ Revision Hip Replacement _____

Knee Arthroscopy _____ Open Reduction Internal Fixation of _____

Other _____

_____

Patient is cleared for surgery from cardiac standpoint

Date: _____

Comments:

_____

_____

_____

Doctor Name: _____ Signature: _____ Date/Time: _____

CONTACT OUR OFFICE IF YOU HAVE ANY QUESTIONS. THANK YOU.

SIERRA VIEW MEDICAL CENTER
Porterville, California 93257
HKC CARDIAC CLEARANCE

Sierra View Medical Center is a service of the Sierra View Local Health Care District.

PATIENT'S LABEL

Sierra View Hip and Knee Center

Timothy L. Tan MD
263 Pearson Dr. Suite 206, Porterville, CA 93257
For Immediate Consult: (559) 788-6081
Fax: 559-544-1004 NPI number: 1023404910

Date: _____ DOB: _____

Name: _____ Insurance: _____

Phone: _____

☐ Right ☐ Left ☐ Bilateral

Diagnosis: _____

☐ Pre-Op ☐ Post-Op ☐ Non-Op

Procedure

☐ Total Hip Arthroplasty
☐ Total Knee Arthroplasty
☐ Unilateral Knee Arthroplasty
☐ Hemiarthroplasty
☐ ORIF
☐ I&D
☐ Hip Arthroscopy
☐ Core Decompression
☐ Other: _____

☐ Revision Total Hip Arthroplasty
☐ Revision Total Knee Arthroplasty
☐ Partial Knee Arthroplasty
☐ Bicompartmental Arthoplasty
☐ Removal of Hardware
☐ Knee Arthroscopy
☐ Open Tendon Repair
☐ Closed Reduction

Weight bearing Status: ☐ Non WB ☐ Toe Touch WB ☐ Partial WB of _____ % ☐ Full WB

Assistive Device: ☐ Use at all times ☐ Wean as tolerated
☐ Cane ☐ Walker ☐ Crutches ☐ Other: _____

Restrictions: ☐ Hip Precautions ☐ Anterior ☐ Posterior ☐ Other: _____

Duration: ☐ 2-3 times/ 6 weeks ☐ Provide patient with home exercises

Programs:

☐ See Attached Protocol
☐ ROM
☐ Patellofemoral protocol
☐ Desensitization protocol
☐ Stretching
☐ Strengthening
☐ Isometrics
☐ Home TENS unit
☐ Work Hardening
☐ Independent Activity of Daily Livings
☐ Gait training
☐ Aqua therapy
☐ Modalities as Needed
☐ Other: _____

Comment: _____

Physician Signature: _____ Date: _____ Time: _____

SIERRA VIEW MEDICAL CENTER
Porterville, California 93257
HKC JOINT PT RX

Form # 025522 REV 09/23

Sierra View Medical Center is a service of the Sierra View Local Health Care District.

PATIENT'S LABEL

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Sierra View Hip and Knee Center
Timothy L. Tan MD
263 Pearson Dr. Suite 206, Porterville, CA 93257
For Immediate Consult: (559) 788-6081
Fax: 559-544-1004 NPI number: 1023404910

NAME:_____

DATE:_____

DOB: _____

Upper Extremity

□ Right □ Left □ Bilateral

- ❑ Tennis Elbow Counterforce Brace
- ❑ Regular Shoulder Sling
- ❑ Shoulder Sling with Abduction Pillow (Ultrasling)
- ❑ Hinged Elbow Brace
- ❑ Sarmiento Fracture Brace
- ❑ Cockup wrist splint
- ❑ Other _____

Functional Aids

- ❑ Cane
- ❑ Walker
- ❑ Walker with chair
- ❑ Commode
- ❑ Raised toilet seat
- ❑ Wheelchair
- ❑ Powered wheelchair
- ❑ Other _____

_____

_____

Lower Extremity Brace

□ Right □ Left □ Bilateral

- ❑ Hip Abduction Brace
- ❑ Knee Immobilizer
- ❑ Medial Unloader Brace
- ❑ Hinged Knee Brace
- ❑ Cam Boot Air
- ❑ Hard Soled Shoe
- ❑ Ankle Stirrup
- ❑ Ankle Foot Orthosis (AFO)
- ❑ Lift for shoe _____
- ❑ Other _____

Diagnosis Codes

- ❑ R knee Primary Osteoarthritis -M17.11
- ❑ L knee Primary Osteoarthritis -M17.11
- ❑ BL knee Primary Osteoarthritis -M17.0
- ❑ Aftercare following joint replacement - Z47.1

Other_____

_____

Reason for exam, symptoms or diagnosis? _____

_____

_____

Physician Signature:_____ DATE: _____/_____/_____ TIME: _____

SIERRA VIEW MEDICAL CENTER

Porterville, California 93257

HKC ORTHOTICS ORDER FORM

Form # 025523 REV 09/23

Sierra View Medical Center is a service of the Sierra View Local Health Care District.

PATIENT'S LABEL

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Surgery: Right or Left or Bilateral Location: _____

Knee

- ☐ 27447 Total Knee Replacement
- ☐ 27446 Partial knee replacement
- ☐ 27486 Revision Knee 1 component partial
- ☐ 27487 Revision Knee femoral/tibial Total
- ☐ 27488 Removal of Total knee w insertion of spacer
- ☐ 27570 Manipulation of knee under anesthesia
- ☐ 27438 Arthroplasty patella with prosthesis
- ☐ 27442 Patellofemoral Arthroplasty
- ☐ 20985 Computer assisted surgical navigation
- ☐ 29881 Arthroscopy knee w menisectomy medial or lateral
- ☐ 29880 Arthroscopy knee w menisectomy medial & lateral

☐ **Incision&Drainage/Other:**

- ☐ 11010 Debridement skin/sub tissue
- ☐ 11011 Debridement skin/sub tissue and muscle
- ☐ 11012 Debridement skin/sub tissue muscle & bone
- ☐ 26990 Incision&Drainage pelvis or hip deep abcess
- ☐ 26991 Incision&Drainage pelvis or hip infected bursa
- ☐ 26992 Incision bone cortex pelvis or hip osteomyl/absc
- ☐ 27301 Incision&Drainage deep abcess thigh/knee
- ☐ 27303 Incision&Drainage deep bone cortex
- ☐ 27486 Lysis of adhesions and lateral release
- ☐ 20680 Removal of Hardware (deep)
- ☐ 20670 Removal of Hardware (superficial)
- ☐ 20694 Removal under anesthesia of external fixation
- ☐ 20690 Application of uniplane (pins/wires)
- ☐ 20692 Application of multiplane external fixation
- ☐ 20985 Computer assisted surgical navigation
- ☐ 27340 Excision of prepatellar bursa
- ☐ 27347 Excision of lesion of meniscus or capsule
- ☐ 27345 Excision of synovial cyst

☐ **Arthroscopy:**

- ☐ 29870 Arthroscopy knee diagnostic w or wo biopsy
- ☐ 29871 Arthroscopy knee surgical for infect lavage&drain
- ☐ 29874 Arthroscopy knee for remov loose, foreign body
- ☐ 29875 Arthroscopy knee synovect limited
- ☐ 29876 Arthroscopy knee synovect major 2 or more compart
- ☐ 29877 Arthroscopy knee debridement, shaving artic joint
- ☐ 29880 Arthroscopy knee w menisectomy, med&lat
- ☐ 29881 Arthroscopy knee w menisectomy, med or lat
- ☐ 29882 Arthroscopy knee w meniscus rep, med or lat
- ☐ 29883 Arthroscopy knee w meniscal rep, med or lat
- ☐ 29884 Arthroscopy knee w lysis of adhesions w,wo manip

☐ **Knee Other:**

- ☐ 27385 Suture of quad or hamstring rupture primary
- ☐ 27386 Suture of quad or hamstring rupture secondary
- ☐ 27405 Repair primary torn ligam &/or capsule knee coll
- ☐ 27407 Repair primary torn ligam &/or capsule knee cruc
- ☐ 27415 Osteochondral allograft knee
- ☐ 27416 Osteochondral autograft knee
- ☐ 27418 Anterior tibial tubercleplasty
- ☐ 27420 Recon of dislocating patella
- ☐ 27422 Recon dislocating patella w extensor alignment
- ☐ 27430 Quadricepsplasty
- ☐ 27027 Decompression fasciotomy pelvic unilateral
- ☐ 27033 Arthrotomy hip includ explor or remov loose body
- ☐ 27310 Arthotomy knee w explor drainge of foreign body
- ☐ 27385 Suture of quad or hamstring muscle rupture prim
- ☐ 27403 Arthrotomy w meniscus repair, knee
- ☐ 27405 Repair prim torn ligam &/or capsule,knee,collat
- ☐ 27470 Repair non or malunion femur dist head/neck
- ☐ 27472 Rep non or malunion femur dist head/neck w graft
- ☐ 27496 Decompr fasciotomy thigh knee 1 compartment
- ☐ 27498 Decomp fasciotomy thigh/knee mult compartments
- ☐ 27590 Amputation thigh through femur any level
- ☐ 27594 Amputation thigh-femur any level, 2ndary closure

Hip

- ☐ 27130 Total Hip Replacement
- ☐ 27132 Conversion of previous hip surgery to THA
- ☐ 27134 Revision total hip replace both components
- ☐ 27125 Partial hip replacement (Hemi)
- ☐ 27137 Revision total hip repl acetabular comp only
- ☐ 27138 Revision total hip repl femoral comp only
- ☐ 27091 Removal of hip prosthesis
- ☐ 27265 Closed treat of hip arthroplasty disloc wo anes
- ☐ 27266 Closed treat of hip arthroplasty disloc w anesth
- ☐ 27090 Removal of hip prosthesis (sep procedure)
- ☐ 27236 Hemiarthroplasty for fracture

Fracture Care:

- ☐ 27236 Open treatment of femoral fracture
- ☐ 27235 Percut treatment of femoral fracture
- ☐ 27244 Treatment of inter/per/subtroch femoral fracture
- ☐ 27245 Treatment of inter/per/subtroc fem fract w IM imp
- ☐ 27506 Open treatment of femoral shaft fracture
- ☐ 27507 Closed treatm of fem shaft fract w plates screws
- ☐ 27503 Closed Treat sub/trans fem fract w traction
- ☐ 27248 Open treatment greater trach fract w int fixation
- ☐ 27500 Closed treat fem shaft fracture
- ☐ 27250 Closed treatment hip disloc w/o anesthesia
- ☐ 27252 Closed Treatment hip disloc w anesthesia
- ☐ 27465 Osteoplasty femur shortening
- ☐ 27466 Osteoplasty femur lengthening
- ☐ 27535 Open treatment tibial fracture w fixation
- ☐ 27536 Open treatment tibial fracture bicondyl w fix
- ☐ 27520 Closed treatment of patellar fracture
- ☐ 27759 Treatment of tibial shaft fracture IM implant
- ☐ 27750 Closed treatmen tibial shaft fracture w/o manipul
- ☐ 27752 Closed treatment tibial shft fracture w manipul
- ☐ 27792 Open treatment distal fibul fract w intern fix
- ☐ 27814 Open treatment binall ankle fract w intern fix
- ☐ 27425 Treat inttroch/pertroch or subtro fem frac w IM
- ☐ 27524 Open treatment of patellar fract w internal fix
- ☐ 27509 Percut fix of fem fract dist end, med or lat cond
- ☐ 27193 Closed pelvic ring fracture w/o manipulation
- ☐ 27194 Closed pelvic ring fracture w manipulation
- ☐ 27215 Open iliac spine tuber or wing frac w intern fix
- ☐ 27216 Percut fixation post pelvic ring fract/disloc
- ☐ 27217 Open anterior pelvic fract w internal fix
- ☐ 27218 Open posterior pelvic fracture w internal fix
- ☐ 27220 Closed treatment of acetabulum frac w/o manip
- ☐ 27222 Closed treat of acetabulum frac w manipulation
- ☐ 27226 Open treat post or ant acetabulum wall,int fixat
- ☐ 27227 Open treat 1 column or trans acetabu frac, int fix
- ☐ 27228 Open treat both colum,Ttype or 1 colum+wall aceta
- ☐ 27254 Open treat hip disloc acetab wall frac w,w/o fix
- ☐ 27269 Open treat fem frac prox end,head,int fix
- ☐ 27502 Closed treat fem shaft frac w manip w, w/o skin
- ☐ 27511 Open treat supra/transcondyl fem frac inc int fix
- ☐ 27513 Open treat intercondylar fem frac incl int fix
- ☐ 27514 Open treat fem frac dist end med/lat cond,int fix
- ☐ 27530 Closed treat tibial plateau frac w/o manipulation
- ☐ 27532 Closed treat tib plat frac w,w/o manip w traction
- ☐ 27538 Closed treat intcond spin/tub frac knee w,w/o mani
- ☐ 76000 Fluoroscopy up to 1 hr physician time
- ☐ 76001 Fluoroscopy more than 1 hr physician time

Allergy: Penicillin Sulfa Clinda

Levaquin Bacitracin Augmentin

- ☐ Anesthesia Consult
- ☐ Medical Clearance
- ☐ Cardiac Clearance AUTH _____

Tentative Date of Surgery:

SIERRA VIEW MEDICAL CENTER

Porterville, California 93257

HKC ORTHO ENCOUNTER FORM

Form # 025525 REV 09/23

Sierra View Medical Center is a service of the Sierra View Local Health Care District.

PATIENT'S LABEL

SIERRA VIEW MEDICAL CENTER

HKC ORTHO ENCOUNTER FORM

MRN # _____ ___ Spanish Only

Today's Date: _____

- ☐ New Patient
- ☐ Follow up Visit
- ☐ Post-Op # 1 2 3 X
- ☐ Hip/Knee
- ☐ Shoulder/Elbow
- ☐ X-rays
- ☐ Injections
- ☐ CT MRI ☐
- ☐ EMG/NCT

Seat#1&2 Please Update:
PMD Name&Fax **Insurance** **Cellphone** **WC** **All**

Today's Authorized Codes:

99205 99245 99204 99244 99203
99215 99214 99213

20526 20550 20600 20605
Splint Authorized:

Patient is in Room #
_____

Chief Complaint:

___ **Years old**

Vital Signs: T _____ HR _____ BP ____/____ HT ____ft ____in WT ____lbs BMI ____

New Problem (NP):

Dictation Number / Transcribed MA
_____ / _____

ate of Imaging Xray_____ MRI_____ Date of Original Injury/Onset Symptoms: _____ Date of Surgery 1st:_____

Occupation_____
Hobbies_____
Pain: (1-10 Severity) _____
Duration: _____

Location:
_____ Groin
_____ Inside (medial)
_____ Outside (lateral)
_____ Anterior
_____ Posterior/Buttock

Quality:
_____ Sharp
_____ Dull
_____ Aching
_____ Burning
_____ Shocking/Electric/Tingling

Timing:
_____ Night pain
_____ Increases with Activity
_____ Stairs

Associated signs/symptoms:
_____ None
_____ Numbness
_____ Weakness
_____ Stiffness
_____ Other: _____

Ambulatory device
☐None ☐Cane ☐Walker

Walking distance
_____blocks or _____minutes

☐ Injections#_____ of injections
Improved ☐Yes ☐No

☐PT_____ of months
Improved ☐Yes ☐No

☐NSAIDS
Improved ☐Yes ☐No

Red flag PMH
___ Smoker ___ cigarettes a day
___ MI
___ DVT or PE
___ Afib or Blood Thinners_____
___ COPD

Prior Knee or Hip Surgeries:

Worksheet/Previous

h/o , s/p :

New Problem (NP):

Copy New XRay/CT/MRI Report:

Workup Ordered:

EMG / NCT: B/L RT LT

Brace:

HKB Immobilizer Unloader

Diagnostics:

XRAY

MRI

CT Scan

Hip injection

Knee aspiration Hip aspiration

Bloodwork: ESR CRP

WC Adjuster:

QME Requested

MMI Pending :

Outgoing Referral :
Call MD:

Patient is Transferred to ER/Ambulance

Patient is Discharged from this Office

Refer to:
[ ]PMR [ ]Spine [ ]Neuro

Rx:
Voltaren Mobic PT RFA

A= Auth P=Pending Dispensed ___

BL hip OA– M16.0
R hip OA –M16.11
L hip OA – Z47.1
R hip AVN – M87.051
L hip AVN – M87.052
M16.12 - Aftercare jt

R hip pain-M25.551
L hip pain-M25.552
R THA-Z96.641
L THA-Z96.642

R knee OA-M17.11
L knee OA-M17.12
BL knee OA -M17.0
Baker's cyst R-M71.21 L-M71.22
Knee pain- R-M25.561 L-M25.562
R TKA-Z96.651 L-Z96.652

Next Visit: Needed Codes

99215 x3 LaSalle Dignity Health
99214 x3 CCIPA WC

20610 x2Joint injection/aspiration
J7325 x2 Synvisc One
83516, 86140 Synovasure
RK LK RH LH

Follow Up: 1D 1W 2W 3W 4W
6W 2M 90Days 3M 6M 1Y

Office: Visalia Tulare Hanford

Next Visit J L H T F M

Schedule Surgery: _____ ASAP
Always Make Copy for Scheduling

ECW Manager Task:_____ **Last Visit:**_____

Notes: _____

Today's Work Status:
Regular Duty: _____
Current Unchanged Duty: _____
Light Duty: _____
Medium Duty: _____
One Hand Only Duty: _____
Off Work: _____

SIERRA VIEW MEDICAL CENTER
Porterville, California 93257

HKC ORTHO ENCOUNTER FORM

Form # 025525 REV 09/23

Sierra View Medical Center is a service of the Sierra View Local Health Care District.

PATIENT'S LABEL

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Sierra View Hip and Knee Center

Timothy L. Tan MD
263 Pearson Dr. Suite 206, Porterville, CA 93257
For Immediate Consult: (559) 788-6081
Fax: 559-544-1004 NPI number: 1023404910

RECORDS AND AUTHORIZATION MUST BE RECEIVED PRIOR TO SCHEDULING

Referral Information:

Requesting Physician:_____ NPI#:_____ Date of Referral:_____

Office Contact:_____ Office PH#: _____ Office Fax#:_____

Patient Information

Name (Last, First): _____ DOB: _____ SSN#: _____

Address: _____ City: _____ ZIP: _____

Contact Numbers: (MUST PROVIDE AT LEAST 2) _____

Insurance Information:

Primary Insurance: _____ Subscriber#: _____

Secondary Insurance: _____ Subscriber#: _____

Guarantor Name: _____ Relationship: _____

DOB: _____ SSN#: (NECESSARY)_____

Lorem ipsum

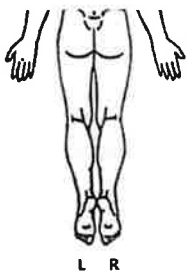
PLEASE CIRCLE: HMO PPO EPO Medi-Care Medi-Cal Medicare Managed Care Medi-Cal Managed Care

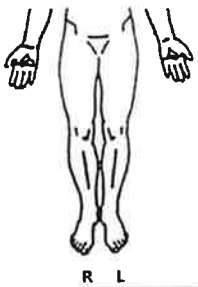
Has authorization been obtained? ☐ **YES** ☐ **NO** ☐ **Not required**

Chief Complaint/Reason for Referral:

Diagnosis: _____

Please circle body part





SIERRA VIEW MEDICAL CENTER
Porterville, California 93257
HKC REFERRAL FORM
Form # 025527 REV 09/23

Sierra View Medical Center is a service of the Sierra View Local Health Care District.

PATIENT'S LABEL

SIERRA VIEW MEDICAL CENTER
NOTICE OF PRIVACY PRACTICES

NOTICE OF PRIVACY PRACTICES

Effective June 1, 2018

This Privacy Notice describes the practices of all employees, staff, and other Sierra View Medical Center (SVMC) personnel, any health care professional authorized to enter information in your SVMC chart, all departments, units and facilities of SVMC, any member of a volunteer group we allow to help you while you are using SVMC services, and all physicians, residents, medical students, students, and allied health professional who provide care at any SVMC facility.

Your medical and mental health treatment information and records are personal and private. Sierra View Medical Center is committed to protecting your health information. The medical and mental health information we create and maintain is known as Protected Health Information/electronic Protected Health Information or PHI/ePHI. We are required by Federal and State laws to protect the privacy of your medical and mental health information and obtain a signed authorization by you for certain disclosures.

We are required by law to provide you with this Notice of our legal duties and privacy practices with respect to your medical and mental health information. This Notice explains how we may legally use and disclose your protected health information and your rights regarding the privacy of your protected health information. We are required to follow all the terms of this notice. We reserve the right to change the provisions of this Notice and make it effective for all protected health information we maintain.

The information privacy practices described in this Notice will be followed by:

- Any health care professional who treats you at any of our locations
- All facilities, departments and units, including hospitals, surgical centers, clinics, and other affiliates
- All workforce members such as employees, medical staff, trainees, students, volunteers, and other persons under our direct control whether or not they are paid by us
- Other health care providers that have agreed to abide by this Notice of Privacy Practices

If you have any questions and/or would like additional information, you may contact the Chief Privacy Officer at (559)788-6066 or the Privacy Coordinator at (559)791-4706 or the Compliance Hot Line at (559) 791-4777.

Thank you.

How We May Use And Disclose Your Protected Health Information

The following categories describe different ways that we use and disclose your protected health information. For each category, we will explain what we mean and try to give some examples. Not every use or disclosure in a category will be listed. However, all of the ways we are permitted to use and disclose your protected health information will fall within one of the categories. We will separately describe the ways we use and disclose HIV/AIDS and substance and/or alcohol abuse information later in this Notice.

1. Treatment

We may use and disclose your protected health information to provide, coordinate, or manage your healthcare and any related services. We may also disclose your health information to other providers who may be treating you or involved in your care.

2. Payment

We may use or disclose your protected health information to obtain payment for the health care services provided to you. For example, we may include information with a bill to Medi-Cal or Medicare that identifies you, your diagnosis, and services provided in order to receive payment.

3. Health Care Operations

We may use and disclose your protected health information to support the business activities of Sierra View Medical Center. For example, we may use your protected health information to review and evaluate our treatment and services or to improve the care and services we offer. In addition, we may disclose your health information with other staff or business associates, who perform billing, consulting, auditing, investigatory, and other services for Sierra View Medical Center.

4. Hospital Directory

We may include certain limited information about you in the hospital directory while you are a patient at the hospital. This information may include your name, location in the hospital, your genera condition (e.g., good, fair, etc.) and your religious affiliation. Unless there is a specific written request from you to the contrary, this directory information, except for your religious affiliation, may also be released to people who ask for you by name. Your religious affiliation may be given to a member of the clergy, such as a priest or rabbi, even if they don't ask for you by name. This information is released so your family, friends and clergy can visit you in the hospital and generally know how you are doing.

5. Fundraising Activities

We may use information about you, or disclose such information to a foundation related to the hospital, to contact you in an effort to raise money for the hospital and its operations. You have the right to opt out of receiving fundraising communications. If you receive a fundraising communication, it will tell you how to opt out.

6. Marketing And Sale

Most uses and disclosures of medical information including uses of patients photographs for marketing purposes, and disclosures that constitute a sale of medical information, require your authorization.

7. Required by Law

We will use and disclose your protected health information when required by Federal, State, or local law.

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8. Health Oversight Activities

We may disclose your protected health information to Federal or State agencies that audit, investigate, and inspect government health benefit programs.

9. Public Health Activities

We may use and disclose your protected health information to public health authorities or government agencies for reporting certain diseases, injuries, illnesses, and events as required by law. For example, we may disclose your medical information to a local government agency in order to assist the agency during the investigation of an outbreak of disease in the area.

10. Victims of Abuse, Neglect, or Domestic Violence

We may disclose your protected health information to other government agencies to report suspected abuse, neglect, or domestic violence. We will only disclose this information if you agree, if the law requires us to, or when it is necessary to protect someone from serious harm.

11. Lawsuits and Legal Actions

We may disclose your protected health information in response to a court order, subpoena, or other lawful process, as allowed by law, for legal proceedings.

12. Law Enforcement

We may disclose your protected health information to law enforcement officials, such as the police, sheriff, to Immigration and Custom's Enforcement (ICE), or FBI, in response to a search warrant or court order, to locate or identify a missing person, a suspect, or a fugitive. In addition, we may disclose your information to report a crime that happens at our clinics or offices, or to report certain types of wounds, injuries, or deaths that may result from a crime.

13. Coroners, Medical Examiners, and Funeral Directors

We may disclose your protected health information to funeral directors, coroners, and medical examiners to identify a dead person, determine what caused the death, or for other official duties.

14. Organ and Tissue Donation

We may disclose your protected health information to organizations that take care of organ, eye, or tissue donations and transplants.

15. Research

We may use and disclose your protected health information for research, if approved by an Institutional Review Board (IRB). An IRB is a committee responsible for reviewing the research proposal and establishing protocols to ensure the privacy of your protected health information.

16. To Stop a Serious Threat to Health or Safety

We may use or disclose your protected health information if it is necessary to lessen the imminent threat of a serious threat to health or safety.

17. Inmates

If you are an inmate of a correctional institution, we may disclose your protected health information to the correctional institution to protect your health and safety, or to protect the health and safety of others at the institution.

18. Military Activity and National Security

If you are or were a member of the armed forces, we may disclose your protected health information to military authorities. We may also share your protected health information with authorized Federal officials when necessary for national security, intelligence activities, or the protection of the President or other government officials.

19. Government Programs for Public Benefits

We may use or disclose your protected health information to help you qualify for government benefit programs, such as Medicare, Medi-Cal, Supplemental Security Income, or other benefits or services available. We may also contact you to tell you about possible treatment options or health-related benefits or services, upon written authorization.

20. Workers' Compensation

We will use and disclose your protected health information for workers' compensation or similar programs that provide benefits for work-related injuries or illness.

21. Family and Friends Involved in or Paying for Your Care

We may disclose your protected health information to a friend, family member, or any other person you identify as being involved with your medical care or payment for care. For example, you may bring a friend or family member to your appointment and have that person in the exam room while talking with a health care provider. You may inform us verbally or in writing if you object to disclosures to your family and friends.

22. Disaster Relief

We may disclose your protected health information to public or private entities in a disaster to provide needed medical care or to help you find members of your family.

23. Appointment Reminders

We may use the contact information that you provided us to remind you of your upcoming medical appointments with Sierra View Medical Center.

24. Immunization Records

We may disclose your child's proof of immunization to their school, if State or other law requires the school to have such information prior to admitting your child as a student. We will obtain the parent's or guardian's authorization prior to doing so, though this may be done informally.

Uses And Disclosures Of Your Protected Health Information Requiring Your Permission

We will obtain your written permission through an authorization for other uses and disclosures of your protected health information not covered by this Notice. You may revoke the authorization in writing at any time and we will stop disclosing protected health information about you for the reasons stated in you written authorization. Any disclosures made prior to the revocation are not affected by the revocation. We are also required to retain our records of the care you receive from Sierra View Medical Center.

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Uses And Disclosures Of HIV/AIDS Information

We may disclose any public health records relating to HIV/AIDS we develop or acquire that contain your protected health information as provided by law for public health purposes or to other public health agencies or corroborating medical researchers when the information is necessary to carry out their duties in investigation, control, or surveillance of disease.

Your physician who orders an HIV test on your behalf may disclose the result of your HIV test to your health care providers for purposes related to your diagnosis, care, or treatment.

Uses And Disclosures Of Your Substance And Alcohol Abuse Information

The confidentiality of your alcohol and drug abuse records we maintain is protected by Federal law and regulations. Generally, we are not allowed to disclose to an outside person your participation in the program or identify you as an alcohol or drug abuser unless:

(1) You consent in writing;

(2) The disclosure is allowed by a court order; or

(3) The disclosure is made to medical personnel in a medical emergency or to qualified personnel for research, audit, or program evaluation.

Federal law and regulations do not protect any information about a crime committed by you either at our program or against any person who works for the program or about any threat to commit such a crime.

Federal laws and regulations do not protect any information about suspected child abuse or neglect from being reported under State law to appropriate State or local authorities.

Your Rights Regarding Protected Health Information About You

1. Right to Inspect and Copy

You have the right to inspect and copy your protected health information in our designated record set, which includes medical and billing records, as long as we maintain that information. You have the right to access your records in any format that the Sierra View Medical Center maintains them in and you may direct them to be sent to a third party. A request must be submitted in writing and a fee may be charged for the costs of copying, mailing, and for any other supplies used in fulfilling your request. We may deny your request to inspect and copy your records. If this occurs, we will send you a written statement as to why and we will explain your right, if any, to have the denial reviewed.

2. Right to Request an Amendment

You have the right to request that we amend your protected health information if you feel that it is incomplete or inaccurate. The request must be in writing and provide reasons that support your request including what information is incomplete or inaccurate.

We may deny your request if it is not in writing or does not include a reason to support the request. We may also deny your request if:

- The information is correct and accurate.
- The information was not created by us.
- The person who created it is no longer available to make the amendment.
- The information is not part of the records you are permitted to inspect and copy.

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If we deny your request for amendment, you have the right to file a written addendum, not to exceed five (5) pages. You may request in writing that the written addendum be added to your medical records, along with your original request to change your medical information and the written denial to make the change.

3. Right to an Accounting of Disclosures

You have the right to request an "accounting of disclosures" which is a list of disclosures we made of your protected health information. The request must be made in writing and can only include disclosures that occurred between the date of your request and up to six years before this date, but not before April 14, 2003. The list will not include disclosures:

- Based on your written authorization;
- To treat you or to receive payment for your treatment;
- For certain business reasons;
- To family members or friends involved in your medical treatment or care;
- To jails, prisons, or law enforcement; or
- For reasons related to legal actions.

For Electronic Health Records (EHR), the accounting of disclosures would also include disclosures of your protected health information made to carry out treatment, payment, and health care operations. This requirement is limited to disclosures within the three (3) year period prior to your request and after January 1, 2014.

You can request one free accounting of disclosures in a 12 month period, but may be charged for additional lists.

4. Right to Request Restrictions

You have the right to request a restriction or limitation on how we use or disclose your protected health information for treatment, payment, or health care operations. For example, you could ask us to limit the information we share with someone who is involved in your care or the payment for your care. For example, you might ask that we limit disclosures to your spouse. We may ask that you give us your request in writing. If we agree to your request, we will not use or disclose the protected health information in violation of such restriction except if we believe this information is required to provide you with necessary medical treatment or care.

We are not required to agree to your request except that you have the right to restrict disclosures to a Health Plan or its business associate if you or someone on your behalf pays out of pocket in full for the health care item or service unless we are required by law to disclose the protected health information. We require the payment be made in full at the time of the request for restriction. If payment is not made, the restriction will be void and disclosure of protected health information will be made to your Health Plan for payment. In some cases where a restriction of disclosure cannot be made or involves another party, we will discuss with you in detail.

5. Right to Request Confidential Communications

You have the right to request how we communicate with you to preserve your privacy. For example, you may request that we call you only at your work number, or send mail to a special address. Your request must be made in writing and must specify how or where we are to contact you. We will accommodate all reasonable requests.

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6. Right to Revoke an Authorization

You have the right to take back or revoke your written authorization to use and disclose your protected health information at any time. You must let us know in writing. If you take back your written authorization, we will stop sharing your protected health information. However, we cannot take back any information already used or shared while the authorization was valid.

Sierra View Medical Center is required by law to keep a record of the medical treatment you receive from the facility, whether or not you give us written permission to use or share it. You do not have the right to have information removed from your record.

7. Right to a Paper Copy of this Notice

You have the right to receive a paper copy of this notice any time you request it, unless you are an inmate at the jail.

8. Breach Notification

In the event of a breach of your unsecured protected health information, Sierra View Medical Center will notify you of the circumstances of the breach.

9. Right to File a Complaint

If you believe your privacy rights have been violated, you may file a complaint with the hospital or with the Secretary of State of the U.S. Department of Health and Human Services. To file a complaint with the hospital, contact the Chief Privacy Officer at (559)788-6066, the Privacy Coordinator at (559)791-4706, the Compliance Hot Line at (559)791-4777, or in writing to Sierra View Medical Center, c/o The Chief Privacy Officer, 465 W. Putnam, Porterville, California 93257.

You will not be retaliated against for filing a complaint.

Our Responsibilities

We must follow the terms of this Notice while it is in effect. We reserve the right to change this Notice and our privacy practices at any time. Changes in our privacy practices will apply to any protected health information we already have and to protected health information we create or receive in the future. We will also post and make the new Notice available at Sierra View Medical Center locations in the waiting areas or at the reception desk. The Notice will also be available on Sierra View Medical Center's website at *http://www.sierra-view.com/NoticeofPrivacyPractices*.

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MEDICAL EXECUTIVE COMMITTEE	10/04/2023
BOARD OF DIRECTORS APPROVAL	
	10/24/2023
BINDUSAGAR REDDY, MD, CHAIRMAN	DATE

SIERRA VIEW MEDICAL CENTER
CONSENT AGENDA REPORT FOR
October 24, 2023 BOARD APPROVAL

The following Policies/Procedures/Protocols/Plans/Forms have been reviewed by the Medical Executive Committee and are being submitted to the Board of Directors for approval:

		Pages	Action
I.	**Policies**:		**APPROVE**
	• Child Abandonment/Safe-Surrender of Newborns	1-3	↓
	• Clean Catch Urine Collection for Urinalysis	4	
	• Compounded Sterile Preparation: Quality Assurance Program	5-9	
	• Criteria for Collection of Stool for Culture	10-11	
	• Criteria for Rejection of Lab Specimens	12-15	
	• Critical Results (Adult) of Tests and Diagnostic Procedures, Reporting of	16-21	
	• Deaths in the ED	22-24	
	• Department Staffing	25-26	
	• Documentation of Care in the Emergency Department	27-28	
	• Education/Discharge Instructions	29-30	
	• Emergency Assessment and Reassessment	31-36	
	• Equipment and Supplies	37-40	
	• Fentanyl Transdermal Patch Use	41-42	
	• Guidelines for Product Dating	43-46	
	• IV Preparation and Dispensing	47-60	
	• Infiltrate Management	61-68	
	• Iron Dextran	69-71	
	• Management of Radiographic Contrast Media	72-73	
	• Medication Procurement, Storage, Distribution and Control	74-86	
	• Nasogastric/Nasointestinal Tube Insertion and Placement Verification Utilizing the Kangaroo Feeding Tube with Iris Technology in the Adult Patient	87-91	
	• Non-Sterile Compounding	92-100	
	• Patient Bed Placement	101	
	• Patient Elopement	102	
	• Patient Triage (ESI and Comprehensive)	103-105	
	• Sign-Out Protocol for Blood Components	106-107	
	• Sterile Hazardous Drug Handling	108-127	
	• Sterile Products: Education and Competency	128-133	
	• Sterile Products: Sterile Product Quality Assurance	134-150	
	• Venous Blood Collection	151-152	
II.	**Forms**:		
	• Transfer into SVMC Checklist	153-154	

SUBJECT: **CHILD ABANDONMENT/SAFE-SURRENDER OF NEWBORNS**	SECTION: **Page 1 of 3**

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

PURPOSE:

To outline the procedures to be followed when a parent or individual with lawful custody brings a minor child who is seventy-two hours old or younger to the Sierra View Medical Center (SVMC) Emergency Department voluntarily requesting SVMC take physical custody in accordance with Section 1255.7 of the Health and Safety Code, and Section 271.5 of the Penal Code.

POLICY:

1. The Emergency Department at SVMC is designated a "Safe-Surrender Site" in accordance with California State Law.

2. Each safe-surrender site is required to post signs, utilizing a statewide logo that has been adopted by the State Department of Social Services that notifies the public of the location where a minor child 72 hours old or younger may be safely surrendered.

3. In accordance with state law, ANY personnel on duty at a "Safe-Surrender Site" shall accept physical custody of a minor child 72 hours or younger, if a parent or other individual with lawful custody of the child voluntarily surrenders physical custody of the child to personnel who are on duty at the "Safe-Surrender Site".

4. In accordance with state law, a safe-surrender site, or personnel of the safe-surrender site, that accepts custody of a surrendered child shall not be subject to civil, criminal, or administrative liability for accepting the child and caring for the child in the good faith belief that action is required or authorized by state law, including, but not limited to, instances where the child is older than 72 hours or the parent or individual surrendering the child did not have lawful physical custody of the child.

AFFECTED PERSONNEL/AREAS: *EMERGENCY DEPARTMENT DIRECTOR/EMERGENCY DEPARTMENT STAFF*

PROCEDURE:

1. The child shall be registered as "Baby Doe" and an identification bracelet will immediately be put on the child.

2. The person surrendering the child will be given a duplicate of the identification bracelet.

3. SVMC personnel shall provide or make a good faith effort to provide, to the parent or individual surrendering the child a medical information questionnaire.

    a. This may be declined,

    b. Voluntarily filled out and returned at the time the child is surrendered, or

    c. Later filled out and in an envelope provided for this purpose (with ID code).

4. No identifying information shall be required of the person surrendering the child (State Law states: *HSC 1255.7 (k) Any identifying information that pertains to a parent or individual who surrenders a child pursuant to this section, that is obtained as a result of the questionnaire described in paragraph (3) of subdivision (b) or in any other manner, is confidential, shall be exempt from disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code), and shall not be disclosed by any personnel of a safe-surrender site that accepts custody of a child pursuant to this section.)*

5. Every questionnaire provided to the person surrendering the child shall have the following notice in no less than 12-point type:

   NOTICE: THE BABY YOU HAVE BROUGHT IN TODAY MAY HAVE SERIOUS MEDICAL NEEDS IN THE FUTURE THAT WE DON'T KNOW ABOUT TODAY. SOME ILLNESSES, INCLUDING CANCER, ARE BEST TREATED WHEN WE KNOW ABOUT FAMILY MEDICAL HISTORIES. IN ADDITION, SOMETIMES RELATIVES ARE NEEDED FOR LIFE-SAVING TREATMENTS. TO MAKE SURE THIS BABY WILL HAVE A HEALTHY FUTURE, YOUR ASSISTANCE IN COMPLETING THIS QUESTIONNAIRE FULLY IS ESSENTIAL. THANK YOU.

6. Ensure a Medical Screening Examination is performed, and all necessary medical care, including transfer to another facility as needed, is provided.

7. The consent of the parent or other relative/guardian is not required to provide care to the child.

8. As soon as possible, but no later than 48 hours, Tulare County Child Protective Services will be notified that the child is at the safe-surrender site.

9. Any medical information pertinent to the child's health, including, but not limited to, information obtained on the medical information questionnaire shall be provided to Tulare County Child Protective Services.

10. Any personal identifying information that pertains to a parent or person surrendering a child shall be redacted (removed) from any medical information provided to Child Protective Services.

11. If, prior to the arrival of Child Protective Services, a parent or individual who has voluntarily surrendered a child to the safe–surrender site, requests that the child be returned, the personnel at the safe-surrender site shall return the child or contact Child Protective Services if any personnel at the safe-surrender site knows or reasonably suspects the child has been a victim of child abuse or neglect. **The voluntary surrendering of a child is not, in and of itself, a sufficient basis for reporting child abuse or neglect.**

ATTACHMENT A: Safe-Surrender Infant Information (English Version)

ATTACHMENT B: Safe-Surrender Infant Information (Spanish Version)

REFERENCES:

- Abandonment and Neglect of Children, California Penal Code 271. 5 (2008). https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=PEN&sectionNum=271.5.
- Safely Surrendered Baby Law, California Health and Safety Code, Section 1255.7 (2011). https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=1255.7.

SUBJECT:	SECTION:
CLEAN CATCH URINE COLLECTION FOR URINALYSIS	**Page 1 of 1**

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

POLICY:

All patients will be instructed how to correctly cleanse and collect a urine specimen for urinalysis.

AFFECTED AREAS/PERSONNEL: *ALL CLINICAL EMPLOYEES*

PROCEDURE:

1. ***Collection of Clean-Catch Midstream Urine - Male***

    a. Wash hands thoroughly with soap and water and wipe dry with a paper towel.

    b. Pull back the foreskin (if uncircumcised) and thoroughly cleanse the glans penis with the provided antiseptic towelette.

    c. Begin to urinate. Allow the first stream of urine to flow into the toilet, then place the container under the stream and fill the container 1/4 full.

    d. Do not touch the rim or the inside of the specimen container.

2. ***Collection - Females***

    a. Wash hands thoroughly with soap and water, wipe dry with a paper towel.

    b. Cleanse each side of the urinary meatus, then cleanse meatus with the provided antiseptic towelette, wiping from front to back.

    c. Begin to urinate. Allow the first stream of urine to flow into the toilet, then place the container under the stream and fill the container 1/4 full.

    d. Do not touch the rim or inside of the specimen container.

REFERENCE:

- Turgeon, Mary Louise, Linne & Ringstrud's Clinical Laboratory Science, 8th Edition, 2020.

SUBJECT:	SECTION:
COMPOUNDED STERILE PREPARATION: QUALITY ASSURANCE PROGRAM	***Medication Management (MM)*** **Page 1 of 5**

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

PURPOSE:

To provide guidelines for the pharmacy quality assurance practices related to the preparation of compounded sterile drug products.

DEFINITION:

Quality Assurance – For purposes of these guidelines, quality assurance is the set of activities used to ensure that the processes used in the preparation of sterile drug products lead to products that meet predetermined standards of quality.

BSC - Biological Safety Cabinet, Class II – A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. A BSC used to prepare a CSP must be capable of providing an ISO Class 5 or better environment for preparation of the CSPs.

CAI - Compounding aseptic isolator – A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for compounding of sterile non-HDs.

CACI - Compounding Aseptic Containment Isolator - is a unidirectional HEPA-filtered airflow isolator designed to provide worker protection from exposure to undesirable levels of airborne drug and to provide an aseptic environment for compounding sterile preparations, also known as sterile intravenous preparation hood.

CSP - Compounded Sterile Preparation

PEC - Primary engineering control - A device or zone that provides an ISO Class 5 or better environment through the use on non-turbulent air, unidirectional HEPA-filtered first air for compounding sterile preparations.

RABS - Restricted-access barrier system – An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/ or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples include CAIs and CACIs

POLICY STATEMENT:

It is the policy of Sierra View Medical Center (SVMC) that all pharmacy preparations of compounded sterile products will follow accepted standards of practice by conducting regular quality assurance activities and testing.

PROCEDURE:

A. Quality Assurance will be implemented to evaluate the following:

1) Personnel Qualifications
   - See Sterile Products: Education and Competency

2) Personnel performance. The total number of errors will be reported in the following categories:

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- Wrong Drug or solution
- Wrong Strength
- Wrong Label
- Wrong Expiration Date

3) Equipment and facilities

- Record of daily anteroom countertop sanitizations
- Record of daily cleanings and sanitizations of cleanroom floors
- Record of daily cleanings for PEC
- Record of weekly anteroom cleaning
- Record of weekly wall and ceiling cleaning
- Record of weekly shelf cleaning environment
- Record of daily CAI/BSC pressures and room pressures
- Record of monthly sporicidal cleaning

4) Environment

- Daily record of room temperature and humidity
- Daily record of refrigerator temperature
- Record airflow pressure differentials daily, where they are available, when open for patient care. During non-operational days, continuous monitoring will alarm for an out of range result and Engineering will alert the pharmacist on-call or the Pharmacist-in-Charge (PIC).
- In the event of a parameter excursion, personnel will follow the procedure outlined in: MEDICATION PROCUREMENT, STORAGE, DISTRIBUTION AND CONTROL

4) Pharmacy personnel will be trained annually on:

- Proper garbing (donning and doffing of personal protective equipment (PPE) while in the compounding areas)
- Proper cleaning/disinfecting/decontamination of compounding areas
- USP 797 Appendix V, "Sample Form for Assessing Cleaning and Disinfection Procedures" will be used as an education and competency training tool.

Competency will be validated by written and visual observation and training records shall be retained.

5) Sterility Testing

- End product sampling will be performed once per month. If six months of continuous negative cultures are reported, preparations will be sampled quarterly.
- In the event of a positive culture, the following shall occur:
    - The pharmacy member that compounded the product will not be allowed to compound sterile IV products until:
        - Aseptic Technique Written Quiz is passed (considered passing score is 100%)
        - Broth Dilution testing of aseptic technique yields absence of microbiological contamination.
    - Infection Control and Quality will be notified.

6) Compounded sterile preparation analysis

- Randomly-selected compounded sterile preparations will be subjected to qualitative and quantitative analysis at least on a quarterly basis. Testing shall include:
    - Potency Testing
    - Comparison of sampled concentration to labeled concentration
    - Endotoxin Testing
    - Any products failing to meet minimum standards will be reviewed by the Pharmacist-in-Charge and the following corrective actions will be taken:
        - ☐ Failed Potency and/or Concentration Test:
            - Review procedure with personnel
            - Review master formula
            - Repeat procedure under Pharmacist-in-Charge's supervision
            - Resubmit for analysis
        - ☐ Failed Endotoxin Test:

- The pharmacy member that compounded the product will not be allowed to compound sterile IV products until:
    - Aseptic Technique Written Quiz is passed
    - Broth Dilution testing of Aseptic Technique yields absence of microbiological contamination.
- Infection Control and Quality will be notified.

7) Recall procedures

- Recalls will be handled as per SVMC policy DRUG RECALL PROCEDURE.
- Per B&P 4127.1, Pharmacy will provide any recall notice for sterile drug products it has compounded to the Board within 12 hours of the notice.

8) Adverse Events and Complaints

- Adverse events related to CSPs will be reported into the hospital's incident reporting software for review.
    - Serious or unexpected adverse events with CSPs will be reported to the Food and Drug Administration (FDA) through the MedWatch program for human drugs.
- The PIC will review all complaints related to CSPs and determine if the complaint indicates a quality problem with CSP.
    - If a quality problem is discovered:
        - A corrective action plan will be initiated immediately, which may include:
            - A recall of all CSPs that may have been affected
            - A suspension of compounding
    - A written record of the complaint must be kept and contain:
        - The name of the complainant
        - Date received
        - Nature of complaint
        - Response to the complaint
        - Name and strength of the CSP, prescription number
        - Findings of investigation
        - Record of complaint must be kept so it is readily retrievable
        - A CSP returned with a complaint must be quarantined until it is destroyed AFTER the investigation.
    - Per B&P 4127.1, adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be reported to the Board of Pharmacy within 12 hours.

9) Validation of beyond-use-dates

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- Beyond-use-dates will be reviewed periodically with a complete update of current manufacturers and/or peer-reviewed literature.

- Any changes identified in the interim time period will result in the immediate updating of the table found in GUIDELINES FOR PRODUCT DATING or STERILE PRODUCTS_EDUCATION AND COMPETENCY.

DOCUMENTATION:

A. Training record retention shall be maintained in employee files. Re-training will be performed per USP Chapter 797.

B. All compounding logs and chart records shall be retained for three years and shall be filed alphabetically by generic name.

C. RABS or BSCs shall be recertified by a qualified person every six months, whenever it is moved, or if filter damage is suspected. Specific tests are used to certify airflow velocity and HEPA filter integrity. Records of certification shall be retained for three years.

EDUCATION:

SVMC Staff: All pharmacists and pharmacy technicians will receive education regarding the indicators used to track quality assurance of pharmacy prepared sterile drug products. All pharmacy staff will sign an acknowledgement form indicating that they understand and will comply with the policy.

REFERENCES:

- The Joint Commission (2022). Hospital accreditation standards. Joint Commission Resources. Oak Brook, IL.
- Pharmacy Law: California Edition. (2023) San Clemente, California: Law Tech Publishing Group.
- USP 797. (n.d.). Retrieved March 20 6, 2023 from http://www.usp.org/compounding/general-chapter-797.

CROSS REFERENCES:

- Drug Recall Procedure – SVMC Policy and Procedures
- Medication Procurement, Storage, Distribution and Control – SVMC Policy and Procedures
- Guidelines for Product Dating – SVMC Policy and Procedures

SUBJECT: **CRITERIA FOR COLLECTION OF STOOL FOR CULTURE**	SECTION: **Page 1 of 2**

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

POLICY:

SPECIMEN CONTAINER:

A stool preservative such as Cary Blair stool transport medium (preferred) or a clean, leak-proof container with a tight fitting lid.

AFFECTED AREAS/PERSONNEL: *ALL EMPLOYEES*

PROCEDURE:

- A bedpan is an ideal initial collection container provided it has been thoroughly cleaned, and the patient is cautioned against contaminating the specimen with urine. A clean, wide mouthed container or a plastic bag or plastic wrap placed over the toilet seat is also acceptable. Note: do not use toilet paper to collect stool, because it may be impregnated with barium salts, which are inhibitory to some fecal pathogens.
- An appropriate (i.e. bloody, slimy, watery) area of stool should be selected and sampled with the collection spoon provided in the cap of the transport medium container. Add sufficient specimen to bring the liquid level up to the "Add Specimen to this Line" mark. This will result in approximately 5 ml of sample.
- Tighten the cap and agitate the vial to ensure that the specimen is adequately mixed. The specimen should appear homogenous.
- Label the specimen, and transport the specimen to the laboratory.
- If submitting specimen in a clean, leak proof container, submit at least 5 ml of diarrheal stool or a walnut-sized portion of formed stool.

PROCEDURE NOTES:

- Specimens collected after antibiotic therapy has been initiated may be contraindicated for successful recovery of organisms.
- Fecal cultures should not be performed for patients being treated with broad-spectrum antimicrobial agents, because it is likely that the antimicrobial therapy is responsible for the diarrhea.
- Stools from inpatients who have been in the hospital for >3 days are of limited value unless the patient is known to be human immunodeficiency virus positive or in cases of a cluster epidemic within the hospital. Consider C. difficile testing as an alternative to routine microbiologic studies.

CRITERIA FOR SPECIMEN REJECTION:

When a specimen is rejected for any of the reasons listed below, the nursing unit will be notified by phone, giving the reason for the rejection, and a new specimen will be requested.

- Specimen not in transport medium received >2 hours after collection. Changes occur that are detrimental to most Shigella spp.
- Specimens in transport medium received >24 hours after collection. Recovery of pathogens may be compromised.
- If the transport vial indicator has turned yellow. Shigella organisms are killed at low pH.
- Hard, solid stools that cannot be sampled for inoculation.
- Stools containing barium. Wait one week after barium before collecting specimen.
- Specimens contaminated with urine or water from the toilet.

REFERENCES:

- Tille, Patricia M., Bailey and Scott's Diagnostic Microbiology, C.V. Mosby Co., St. Louis, Missouri, 15th edition, 2021.
- Isenberg, Henry D., Clinical Microbiology Procedures Handbook, American Society for Microbiology, 4th Edition, 2016.
- Murray, Patrick R., Manual of Clinical Microbiology, American Society for Microbiology, 12th edition, 2019.
- Remel, Inc. Cary Blair Transport Medium package insert, IFU 21610, Revision 10/25/12.

SUBJECT: **CRITERIA FOR REJECTION OF LAB SPECIMENS**	SECTION: **Page 1 of 4**

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

PURPOSE:

To ensure the integrity of patient specimens and the achievement of accurate results.

POLICY:

A. The lab will reject a specimen for any of the reasons below.

B. When the physician, nurse, or patient is responsible for the collection and the specimen is rejected, the nursing unit or physician's office will be notified by phone and a new specimen will be requested.

C. In the event a physician insists a procedure be run on a specimen where results might be compromised, the condition of the specimen must be noted on the patient's lab report.

AFFECTED PERSONNEL/AREAS: *LABORATORY STAFF, NURSING STAFF, PHYSICIANS*

SPECIMEN CRITERIA:

A. All specimens must be properly labeled and submitted in conjunction with a suitable electronic or paper request.

1. Outpatient Referrals:

   a. Patient name and date of birth
   b. Date of collection
   c. Time of collection (if applicable)
   d. Source (if applicable)

2. Inpatients:

   a. Patient name and date of birth
   b. Patient account number or other suitable identifier
   c. BBK# and collector's and witnesses mnemonics (for blood bank specimens)
   d. Date and time of collection
   e. Meditech mnemonic of collecting person
   f. Patient location (if applicable)
   g. Pertinent clinical data (if applicable)

B. Within the hospital institution, all specimens not collected by lab personnel shall be transported to the laboratory in sealed plastic biohazard bags.

C. All specimens must be adequate for the testing requested.

Rejection Criteria for Blood Bank Specimens: (Antibody Screen, ABO typing, Crossmatch, Rh)

- Hemolyzed specimen
- Specimen > 48 hours old
- Improper labeling such as missing BBK#, lacking two sets of mnemonics and/or time of collection
- Any sample suspected of contamination with IV fluid

Rejection Criteria for Serology Specimens:

- HIV – whole blood >5 days old
- Mono – contaminated serum or plasma
- RA – contaminated serum or plasma; gross hemolysis; lipemia
- Any sample suspected of contamination with IV fluid

Rejection Criteria for Chemistry Specimens:

- ABG – clotted specimen; inhomogeneous specimen; venous blood
- Amylase – gross hemolysis
- Alcohol – specimen drawn using alcohol prep; received in Lab >20 minutes
- Alkaline Phosphatase – gross hemolysis; serum or plasma in contact with cells >3 hours
- ALT – gross hemolysis; serum or plasma in contact with cells >2 hours
- Ammonia – specimen received in Lab >20 min
- AST – gross hemolysis; serum or plasma in contact with cells >2 hours
- Bilirubin – gross hemolysis; specimens exposed to light >2 hours
- CPK (CK) – gross hemolysis; lipemia; serum in contact with cells >2 hours
- CRP – contaminated serum or plasma; specimen >8 hours old
- Glucose – serum or plasma in contact with cells >2 hours
- HCG – contaminated specimen; specimen >48 hours old
- Iron – hemolysis; serum or plasma >2 hours old
- Lactate – specimen >20 minutes old
- LDH – hemolysis; serum or plasma in contact with cells >2 hours
- Sodium and Potassium – hemolysis, serum or plasma in contact with cells >2 hours; specimen drawn in sodium heparin or EDTA
- Any sample suspected of contamination with IV fluid

Rejection Criteria for Hematology/Coagulation Specimens:

- Blood Counts – clotted specimens; specimens >24 hours old; specimens drawn in other than EDTA
- Smears – no ridges, lines, or holes; leukocytes not evenly distributed; cells broken; too small or too long

- Platelet Count – drawn in other than EDTA; clotted specimen; specimen not mixed; specimen >24 hours old
- Reticulocyte Count – specimen >24 hours old
- PT or PTT – tube not filled to the line; clotted specimen
- Semen – specimen >2 hours old
- Body fluids for cell counts – clotted specimen
- Any sample suspected of being contaminated with IV fluid

Rejection Criteria for Microbiology Specimens:

- Any dry swab
- Labeling on specimen and requisition label do not correlate
- Specimen in improper collection device, container, or transport media
- Specimen not in sterile container
- Collection device outdated
- Insufficient quantity and/or dried specimen
- Specimens exhibiting gross external contamination of the container (spillage)
- Sputum – saliva, mouthwash, or food contamination; specimen doesn't meet gram stain criteria for number of epithelial cells
- Stool – not fresh or not transferred into Cary Blair medium; collected on swab
- Urine – unpreserved specimen >20 minutes after void; specimen in preservative tube >48 hours old

Rejection Criteria for Molecular Diagnostics Specimens:

- Abbott ID NOW COVID-19 RNA – NP swab held at room temperature greater than 1 hour
- Abbott ID NOW Influenza A/B 2 – NP swab held at room temperature greater than 2 hours
- Abbott ID NOW RSV – NP swab held at room temperature greater than 2 hours
- Abbott ID NOW Strep A 2 Rapid Test – Throat swab held at room temperature greater than 3 days
- Abbott COVID-19 Antigen – Nasal swabs held at room temperature greater than 1 hour
- BD Max SARS-CoV-2 PCR – NP swab not put into UTM (universal transport media) and/or held unrefrigerated (2-8 degrees C); specimens greater than 3 days old
- BD Max *Cdiff* – formed stool specimen and/or specimens held at room temperature greater than 48 hours, only loose or liquid stools are acceptable
- BD Max CT/GC/TV Panel – unpreserved urine (not transferred into UVE special collector) >4 hours at room temperature or >24 hours at 2-8 degrees C; endocervical swab
- BD Max Vaginitis Panel – specimen not in UVE special collection kit within 2 hours of colletion

Rejection Criteria for Urinalysis:

- >2 hours without preservative

REFERENCES:

- Garcia, Lynne S (2016). Clinical Microbiology Procedures Handbook, Fourth Edition, Washington, D.C.: American Society for Microbiology.

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- Turgeon, Mary Louise (2020). Clinical Laboratory Science, Eighth Edition, Maryland Heights, MO:

Elsevier Mosby.

- BD C&S urine collection tube package insert (2016)
- Abbott ID NOW package inserts (2020)
- BD Max package inserts (2021)

CROSS REFERENCE:

- The Joint Commission (2020). Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing. NPSG 01.01.01, DC 01.01.01. Joint Commission Resources. Oak Brook, IL.

SUBJECT: **CRITICAL RESULTS (ADULT) OF TESTS AND DIAGNOSTIC PROCEDURES, REPORTING OF**	SECTION: **Page 1 of 6**

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

PURPOSE:

To establish a process for the prompt reporting of critical results to the provider or designee. Additionally, this policy clearly defines critical results for Laboratory, Respiratory, and Radiology/Imaging Services.

POLICY:

It is the policy of SVMC to support systems that protect patient safety, provide excellence in clinical care, and promote collegial communication among care providers. The Medical Staff of SVMC has determined the following clinical tests to be of clinical importance in the treatment of patients under their supervision. *(See Attachment A)*

AFFECTED PERSONNEL/AREAS: *ALL CLINICAL STAFF*

PROCEDURE:

PERSONNEL DESIGNATED TO REPORT, RECEIVE, AND COMMUNICATE RESULTS

Imaging Services

- Radiologist
- Personnel requested by the Radiologist to call or fax result
- Teleradiology
- Teleneurology

Laboratory Services

- Clinical Lab Scientist
- Laboratory Clerk (predominantly outpatient)
- Phlebotomist
- Pathologist

Respiratory Care Services

- Respiratory Care Provider

Nursing Services

- Licensed Nursing Personnel

NOTIFICATION and DOCUMENATION

1. The test results will be reported to the appropriate provider or designee for the following areas within one hour: Emergency Department, all in-patient areas, Cancer Treatment Center and PACU.

2. For inpatients, Imaging, Laboratory, or Respiratory, personnel will call new critical test results to licensed personnel and/or physician caring for the patient. The receiving licensed person or physician will be asked to read back the test result that was given to them. Notification will be documented in the electronic health record.

3. If the nurse receives the critical test value notification, he/she will notify the attending provider and document the notification in the patient's electronic health record.

4. For outpatients, Imaging, Lab, or Respiratory, personnel will phone the ordering physician/physician licensed office staff immediately. The receiving licensed person or physician will be asked to read back the test result that was given to them. Notification will be documented in the electronic health record.

5. **Chain of Command**

   a. In the event a physician is paged and does not respond within 30 minutes, a second attempt will be made and documented. In the event a physician does not respond after the second notification, the care provider will initiate the Medical Staff Chain of Command as listed below and will document who was notified.

      Medical Department Chairperson of ordering MD
      ↓
      Chief of Staff

   b. A QM notification should be completed to record the occurrence.

Testing Area	Alerting Category	Test	Provide Results Within 1 Hour

Chemistry	Always Red (Always potentially life-threatening to patient, even if patient is actively being treated	Glucose (Adult)	HIGH (e.g. >400)
			LOW (e.g. < 50)
		Potassium	HIGH (e.g. >6)
			LOW (e.g. < 2.8)
		Phosphorus	LOW (e.g. < 1.0)
		Sodium⊗	HIGH (e.g. >160)
			LOW (e.g. < 120)
		Bicarbonate#	LOW (e.g. < 10)
	Red on first instance or if increasing*	Bicarbonate#	LOW (e.g. 10-15), first instance*)
		Magnesium	HIGH (e.g. >5), first instance only*. May tolerate higher level for L&D patients
			LOW (e.g. < 1), first instance only*
		Calcium (total or ionized)	HIGH(e.g. >13 total, >6 ionized), first instance only*
			LOW (e.g. <7, <3.5 ionized total), first instance only*
		Troponin*	High, indicative of acute MI, first instance or if value increasing *
		Lactic Acid*	High (e.g. >4), first instance or if value increasing *
		pH	HIGH (e.g. >7.6)
Blood Cord Gases **	Always Red		LOW (e.g. <7.2)
		pO2	LOW (e.g. <60)

Testing Area	Test	Provide Results Within 1 Hour
Toxicology	Acetaminophen	HIGH (e.g. > 50), first instance only*
	Acetone	Positive first instance only*
	Carboxyhemoglobin	HIGH (e.g. >15%), first instance only*
	Ethanol	HIGH (e.g. > 400 mg/dL), first instance only*
	Ethylene Glycol	HIGH (e.g. > 25mg/dL), first instance only*
	Isopropanol	HIGH (e.g. > 40mg/dL), first instance only*
	Lithium	HIGH (e.g. > 1.8), first instance only*
	Methanol	HIGH (e.g. > 20mg/dL), first instance only*

	Salicylate	HIGH (e.g. > 30), first instance only*
Therapeutic Drug Monitoring	Digoxin	HIGH (e.g. > 2.5mg/dL)
	Procainamide	HIGH (e.g. > 12 mcg/mL),
	Procainamide + NAPA	HIGH (e.g. > 30 mcg/mL),
	Quinidine	HIGH (e.g. > 6 mcg/dL),

Other therapeutic drug levels (e.g. Gentamicin levels, anti-epileptic drug levels): Suggest that these be handled by nursing protocol using parameters set by ordering physician or institutional policies. For example, the protocol might instruct nurses to review antibiotic levels within the last 24 hours before administering that specific IV antibiotic. If the latest level exceeds a certain threshold, the nurses should page the responsible physician to obtain permission to administer medication.

Testing Area	Test	Provide Results Within 1 Hour
Hematology	HCT	HIGH (e.g. > 60)
		LOW (e.g. < 22)
		SIGNIFICANT DROP (e.g. > 10)
	Hemoglobin	HIGH (e.g. > 20
		LOW (e.g. <7)
		SIGNIFICANT DROP (e.g. > 3)
	Platelets	HIGH (e.g. > 1000k), first instance only
		LOW (e.g. < 30K), first instance only
	WBC	HIGH (e.g. > 35k), first instance only
		LOW (e.g. < 1K), first instance only
	Malaria/Babesiosis Smear	Positive
Coagulation	INR	HIGH (e.g. > 5)
	PTT	HIGH (e.g.> 120)

Testing Area	Test/Site	Provide Results Within 1 Hour
Stains	CSF	Positive (bacteria or fungus)
	Blood culture	Positive
	Fluids from joint or other body cavity that are normally sterile (except urine)	Positive
	STAT OR Specimens for Gram Smear	Positive
	Indian Ink (for Cryptococcus	Positive
	PCP silver stain	Positive

Cultures	Blood cultures	Positive for bacteria or fungus
	CSF cultures	Positive
	Culture of fluids from joint or other body cavity that are normally sterile (except urine)	Positive
	Wound culture	Positive for clostridium
PCR	HSV PCR	POSITIVE CSF
Antigens/Toxins	Cryptococcus	Positive
	Hemophilus influenza	Positive
	Neisseria Mengitidis	Positive

Testing Area	Test/Site	Provide Results Within 1 Hour
	EKG**	Acute ST segment elevation of 1 mm or more in 2 more contiguous leads, first instance only*
		Acute ST depression of 2 mm or more in 2 or more contiguous leads, first instance only*
		High Grade AV Block (no pacemaker), first instance only*
		Sustained VT
		Torsades des points
		Sustained SVT
		Severe bradycardia (e.g. < 35 beats/min)
		Idioventricular rhythm
		Atrial fibrillation or flutter, first instance only.
	Adult Echocardiogram	Tamponade
		Acute VSD, s/p MI
		Aortic dissection
		Obstructive (clotted) prosthetic heart valve
		Pseudoaneursym
		Papillary muscle rupture, s/p MI

Testing Area	Anatomical Area	Provide Results Within 1 Hour
Radiology	CNS	Cerebral hemorrhage/hematoma – provide results within 30 minutes or ASAP
		Brain tumor (mass effect)
		Acute stroke
		Depressed skull fracture

		Cervical spine fracture
		Spinal cord **compression**
	Neck	Epiglotitis
		Carotid artery dissection
		Critical carotid stenosis
	Breast	
	Chest	Tension pneumothorax
		Aortic dissection
		Pulmonary embolism
		Ruptured aneurysm or impending rupture
		Mediastinal emphysema
	Abdomen	Free Air in abdomen (if no recent surgeries)
		Ischemic bowel
		Appendicitis
		Portal venous air
		Volvulus
		Traumatic visceral injury
		Retroperitoneal hemorrhage
		Bowel obstruction
	Uro-genital	Ectopic pregnancy
		Placental abruption
		Placental Previa near term
		Testicular or ovarian Torsion
		Fetal demise
	Vascular	DVT or vascular occlusion
	Bone	Unstable fracture
	General	Significant Line/ or Tube misplacement (e.g. feeding tube in airway)

REFERENCES:

- Massachusetts Coalition for Prevention of Medical Errors, macoalition.org/communicating-critical-test-results.shtml. 2018.
- The Joint Commission (2022). Hospital accreditation standards. NPSC.02.03.01. Joint Commission Resources. Oak Brook, IL.

SUBJECT: **DEATHS IN THE ED**	SECTION: **Page 1 of 3**

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

PURPOSE:

To outline the steps to be taken in caring for a deceased individual in the Emergency Department (ED).

POLICY:

1. The ED Physician will determine as quickly as possible the viability of the patient and make the pronouncement of death as appropriate.

2. The ED will notify the authorities of all reportable deaths as required by law.

3. The ED will facilitate the timely removal of the body to a mortuary.

4. The ED staff will offer consolation and assistance to the family in their time of grief.

5. The ED staff, in conjunction with Social Services, Case Management, and Pastoral Care, will offer assistance in obtaining religious support for family members.

6. The ED staff will notify the donor network.

AFFECTED PERSONNEL/AREAS: *EMERGENCY DEPARTMENT DIRECTOR/EMERGENCY DEPARTMENT STAFF*

PROCEDURE:

DEAD ON ARRIVAL

1. All patients brought to the ED will be assumed alive until a pronouncement of death has been made by the ED physician.

2. An ED chart will be completed on the patient.

3. A Sierra View Medical Center (SVMC) identification band will be attached to the remains.

4. ED staff will contact the coroner and follow their instructions regarding disposition of the remains.

5. The donor network will be contacted.

CORONER'S CASES

1. Death's reportable to the Coroner's Office include:

    a. The Coroner is contacted for all deaths in the ED.

2. Fetal deaths beyond the 20th week of gestation will be reported. The gestational age is the interval from date of last normal menses to the estimated death date of the fetus.

3. The Tulare County Coroner requests to be informed of fetal deaths when the fetus is 500 grams or greater, and if the length is 28cm or greater.

4. Notification of the Coroner:

   a. Call the Tulare County Sheriff's Department Dispatch Center. They will dispatch the appropriate person to take the report.

   b. Do not release the body to the mortuary until instructed to do so by the Coroner's representative or Deputy Sheriff.

   c. All known facts relating to the significant health history, circumstances surrounding the death, or any other information shall be documented on the patient's chart.

5. Care of the Body:

   a. **Once the victim has been pronounced dead, the body must not be searched.** Determining identification will be the responsibility of the coroner investigators. No valuables (money, jewelry, watches, wallets, etc.) shall be removed or given to the family members. Once the investigation is complete, the coroner will handle release of effects.

   b. **All tubes, IV lines, etc. shall remain in place and undisturbed**. The coroner investigator may approve their removal after completion of their preliminary investigation.

6. Care of the Family:

   a. Persons accompanying the victim should be made comfortable in a quiet room.

   b. If the family is not in the ED and does not know of the patient's situation, they should be contacted by phone and asked to come to the ED. **Notification of death by phone should be avoided**. If identification of the patient or family's location is unknown, it will be the responsibility of the Coroner's office to make the notification.

   c. ED personnel will refer all news media to the SVMC public relations officer or, if after hours, to the House Supervisor.

   d. Informing the family of death is the duty of the physician. Support of nursing personnel is important. If prolonged resuscitation efforts are being done, a nurse should see that the family is kept informed, in lay terms, of current resuscitation efforts. If deemed appropriate by the treatment team, family should be allowed to be at bedside during resuscitation. Such preparation may be helpful to the family and staff.

e. Unless prohibited by law enforcement, family members desiring to view the body should be assisted to do so. Family members should be allowed to view the patient as soon as practicable. Nursing and physician judgment is important.

f. If possible, a staff member should be assigned to assist the family in calling religious assistance, transportation, other family members, etc.

g. Prior to leaving the ED, a responsible family member should be asked to sign all required documents and make known their preference for a mortuary, funeral home, or crematorium. If there is no preference, or the family is not available to make a preference known, the on-call mortuary shall be called by coroner.

Note: The family member should be asked to sign the "Authority for Release of Remains" form which will stay on the individual's medical record. The mortuary also signs the form when the body is picked up.

h. **The DONOR network will be notified of the patient's death. An OPA number will be given by them. This number will be recorded onto the "Authority for Release of Remains" form, electronic medical record, and reported to the House Supervisor.**

REFERENCE:

- California Code of Regulations (2020). Title 22. §70709. Emotional and Attitudinal Support. Retrieved from https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=ID7365A90D4BB11DE8879F88E8B0DAAAE&originationContext=documenttoc&transitionType=Default&contextData=(sc.Default)&bhcp=1.

- California Code of Regulations (2020). Title 22. §70829. Morgue. Retrieved from https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=ID7365A90D4BB11DE8879F88E8B0DAAAE&originationContext=documenttoc&transitionType=Default&contextData=(sc.Default)&bhcp=1.

- California Health and Safety Code, Division 7, Sect(s) 7000-8030. Dead Bodies (1973). https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=7.&title=&part=1.&chapter=5.&article=2.

SUBJECT: **DEPARTMENT STAFFING**	SECTION: **Page 1 of 2**

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

PURPOSE:

To provide guidelines to adjust staffing to patient census based on an acuity system. This system is based on a number system given to each modality of care.

POLICY:

Respiratory Care Services is staffed 24 hours a day, 365 days a year with licensed Respiratory Care Practitioners (RCP), fully certified in Basic and Advanced as well as Pediatric and Neonatal Life Support. Out-patient electroencephalogram (EEG) procedures are scheduled as needed Monday through Friday from 7:00 AM- 4:30 PM.

PROCEDURE:

Each shift is responsible for assessing staffing requirements at least two (2) hours before the next shift. The on-duty lead or manager will update the respiratory census to obtain activity, volume, and staffing requirements for the next on-coming shift. The lead person will assign a procedure count to each patient.

CALCULATION OF STAFFING NEEDS

1. Ensure respiratory census is updated and current.
2. Assign procedure count to each patient.
3. Total all procedures for all patients and patient care areas.

For safety reasons, a minimum of 4 FTEs are scheduled at all times. When shifts are affected by un-excused absences and/or staff leaving early due to illness or emergency, and staffing levels will be less than minimum, the remaining staff will notify the Director/Manager, Lead Respiratory Therapist or House Supervisor, in that order, as soon as possible.

STAFFING GUIDELINES:

Time Workload Units (TLUs)	**Staffing Goals**
0.0-4.5	4 FTEs
4.6-5.5	5 FTEs
5.6-6.5	6 FTEs
6.6-7.5	7 FTEs

SUBJECT: **DEPARTMENT STAFFING**	SECTION: **Page 2 of 2**

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

ADDITIONAL STAFFING:

Additional staffing can be obtained by:

1. Calling in off-duty per diem staff
2. Calling in off-duty full-time staff
3. Considering 4 or 8 hour shift
4. Calling the Director or Manager of Respiratory Care Services

STAFF REDUCTIONS:

1. When making staff reductions, the Director, Manager, or Lead Respiratory Therapist takes into consideration the regular scheduled shifts vs. the overtime (OT) shifts that were covered voluntarily. Decisions to reduce staff will be made in a systematic rotation by leadership. Attempts will be made not to penalize the previously worked OT shifts. All scheduled staff report for duty.
2. Flexing will be determined during the shift as needed in the following order:
   - A. Overtime
   - B. Per diem
   - C. Full time staff

REFERENCE:

- American Association for Respiratory Care (2023). *Safe and Effective Staffing Guide*. "Implementation Resources- The Importance of Accurate Time Standards."

SUBJECT: **DOCUMENTATION OF CARE IN THE EMERGENCY DEPARTMENT**	SECTION: **Page 1 of 2**

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

PURPOSE:

To define the process for documenting patient care in the emergency department.

DEFINITIONS:

1. EMR – Electronic Medical Record
2. CPOE – Computerized Provider Order Entry
3. Patient – Any person who asks, seeks, or is brought to the Emergency Department for medical care.

POLICY:

All patient contact and care rendered in the Emergency Department (ED) will be documented in the appropriate areas on the Electronic Medical Record (EMR) except during downtime procedures (see Meditech Downtime Policy).

AFFECTED PERSONNEL/AREAS: *EMERGENCY DEPARTMENT*

PROCEDURE:

All patients presenting to the ED for medical care will have an Emergency Department Record completed in the EMR, unless presenting during downtime procedure, at which point approved downtime forms will be utilized.

1. ED Consent for Treatment
    a. Any patient presenting to the ED will have a signed "Conditions of Admission" form.
    b. The Conditions of Admission can be signed by the patient, conservator, parent of the minor patient, or the ED Physician who authorizes treatment of a minor obtained under provisions provided for by law.
2. Patient Care Record
    a. The Meditech EMR will be used for all documentation with the exception of:
        i. Downtime (see Meditech Downtime Policy)
        ii. Procedures/interventions not available in Meditech (i.e. Code Blue Forms)

b. Documentation in CPOE portion of Meditech will be completed by Physician, Physician Assistant, Nurse Practitioner, and/or Scribes or through approved telephone or verbal orders given to a licensed nurse.

c. Nursing and all other licensed personnel will document all interventions and narratives in the appropriate areas in the EMR.

Admitted patients waiting in the ED longer than 4 hours because of staffing and/or bed shortages will be treated as a "hold" patient.

1. A "hold" patient will have inpatient orders initiated while waiting in the ED until an inpatient room becomes available.

    a. Effort will be made to have a nurse with inpatient access begin charting on the inpatient EMR for all interventions completed for the "hold" patient.

    b. The House Supervisor can assist inpatient documentation through one of the two following methods:

        i. Relieve an inpatient RN to go to the ED to complete the initial assessment, or

        ii. Complete the initial assessment when rounding in the ED.

REFERENCE

- The Joint Commission (2020). Hospital accreditation standards. Joint Commission Resources. Oak Brook, IL.

SUBJECT: **EDUCATION/DISCHARGE INSTRUCTIONS**	SECTION:

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

PURPOSE:

- To define the process for patient education, and handling of discharge instructions.

POLICY:

All patients discharged from the Emergency Department will receive condition-appropriate instructions for home care and appropriate referrals.

AFFECTED PERSONNEL/AREAS: *ALL ED PHYSICIANS; ALL ED STAFF*

PROCEDURE:

PATIENT IDENTIFICATION:

The nurse is to follow the hospital established two-patient identifier process to assure that the information correlates with the patient information on documents before releasing them to the patient.

PATIENT EDUCATION: (can be achieved through the following methods)

1. Verbal interaction between a nurse and the patient/caregiver.

2. Information sheets: Examples include: Pediatric hydration, hepatitis, vaccinations, measles, antipyretic dosage, seizures, medications, and over-the-counter treatment for head lice.

DISCHARGE INSTRUCTIONS:

1. Verbal instruction to the patient on specific discharge instructions.

2. Patient will (if able) verbally state understanding of discharge instructions.

3. Patient will verbalize and demonstrate any skill given by the nurse as part of discharge instructions (i.e., rectal temperatures on pediatrics).

4. Appropriate follow-up referral/s. The "Physician On-Call List" will be utilized when the patient does not have a primary physician or is requesting another physician.

5. The patient's caregiver may receive instruction in lieu of the patient if the patient is unable to comprehend the instructions.

NOTE: Education/discharge instructions will be documented on the patient's medical record.

REFERENCES:

- Agency for Healthcare Research and Quality. (2017). Improving the emergency department discharge process. Retrieved from https://www.ahrq.gov/professionals/systems/hospital/edenvironmentalscan/ index.html.

- Kornburger, C., Gibson, C., Sadowski, S., Maletta, K., & Klingbeil, C. (2013). Using "teach-back" to promote a safe transition from hospital to home: An evidence-based approach to improving the discharge process. Journal of Pediatric Nursing, 28(3), 282–291. https://doi.org/10.1016/j.pedn.2012.10.007.

SUBJECT:	SECTION:
EMERGENCY ASSESSMENT AND REASSESSMENT	***Emergency Department*** **Page 1 of 6**

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

PURPOSE:

To establish guidelines for initial assessment and reassessment of patients in the Emergency Department (ED).

DEFINITIONS:

Normal Vital Signs

Pulse		
>10 years of age	60 to 100 beats / minute	
	Awake Rate	**Sleeping Rate**
2-10 years	60-140 beats /minute	
3 months – 2 years	100-190 beats/min	
Newborn – 3 months	120 – 160 beats / min.	

Blood Pressure		
	Systolic	**Diastolic**
Adult	90-140 mmHg	60-90 mmHg
Children (1 – 8 years)	80-110 mmHg	
Infants (1-12 months)	70-95 mmHg	
Neonates (1-28 days)	>60 mmHg	

Respirations	
Adult / Adolescent	12 to 16 breaths / minute
School Age Chile	18 to 30 breaths / minute
Preschooler	22-34 breaths / minute
Toddler	24-40 breaths / minute
Infant	30-60 breaths / minute

Pulse Oximtery	
All ages	95-100 %

Glascow Coma Scale		
Adult		**Infant**
Eye Opening	**E**	**Eye Opening**
Spontaneous	4	Spontaneous
To Speech	3	To Speech
To Pain	2	To Pain
No Response	1	No Response
Best motor response	**M**	**Best motor response**
Obeys verbal command	6	Normal movements
Localizes pain	5	Localizes pain
Flexion – withdraws from pain	4	Withdraws from pain
Flexion – abnormal	3	Flexion – Abnormal

Extension	2	Extension
No response	1	No response
Best verbal response	**V**	**Best verbal response**
Oriented and converses	5	Coos, babbles
Disoriented by converses	4	Cries but consolable
Inappropriate words	3	Persistently irritable
Incomprehensible sounds	2	Grunts to pain / restless
No response	1	No response

Revised Trauma Score			
Glascow Coma Scale	Systolic Blood Pressure	Respiratory Rate	Coded Value
13-15	>89	10-29	4
9-12	76-89	>29	3
6-8	50-75	6-9	2
4-5	1-49	1-5	1
3	0	0	0

POLICY:

A. All patients presenting to the Emergency Department for care will be assessed by a Registered Nurse.

B. All patients in the Emergency Department will be reassessed within the guidelines established in this policy.

AFFECTED PERSONNEL/AREAS: *ALL EMERGENCY DEPARTMENT REGISTERED NURSES (RN) AND CERTIFIED NURSING ASSISTANTS (CNAs).*

EQUIPMENT:

- Stethoscope
- Scale
- Blood Pressure Cuff / Monitor
- Equipment for measuring height
- Thermometer

1. Oral (as appropriate)
2. Rectal (as appropriate)
3. Temporal (as appropriate)

- Pulse oximeter

  1. Disposable pulse oximeter probes

PROCEDURE:

A Triage Assessment

1. The triage assessment will be completed by a Registered Nurse in the ED as soon as possible after a person presents to the Emergency Department requesting medical care.

2. The RN will gather a minimum of the following information to determine the patient's severity

   a. Name and Date of Birth

   b. Reason for seeking treatment

   c. ESI Triage Acuity

3. The RN will perform an initial clinical assessment of the chief complaint on each patient entering the ED, collecting subjective and objective data to include, but not limited to:

   a. Date, Presentation Time and Triage Time

   b. Mode of Arrival

   c. Chief Complaint with Triage Notes

   d. Complete Set of Vital Signs (Temperature with route, Pulse with regularity, Respirations with work of breathing, Blood Pressure, O2 saturation with mode, and level of pain.)

   e. Height and weight

   f. Any sudden onset of symptoms

   g. Any pre-arrival treatment

   h. Allergies

   i. Past medical history

j. Last tetanus vaccination if indicated

C. Focused Assessments

1. In addition to the information collected for the Triage Assessment, additional information will be collected as appropriate. This may include, but is not limited to:

a. Primary Care Physician

b. Current medications

c. Last menstrual period in women of child-bearing age

d. Focused assessment will be based on the presenting chief complaint

i. A minimum of the following will be addressed in the focused assessment:

a) Time of assessment

b) A review of the body systems to ***always*** include:

i) Psychosocial

ii) Patient Safety

iii) Pain

iv) Respiratory status

v) Cardiovascular status

vi) Neuro status

c) A review of the following body systems if indicated:

i) Gastrointestinal

ii) Integumentary

iii) Genitourinary

iv) Musculoskeletal

v) EENT (eyes, ears, nose, and throat)

vi) Obstetrical / Gynecological

d) Any subjective notes

e) Educational learning needs

e. Pediatric growth and development and immunizations, if indicated.

f. All trauma patients will be assigned a Glascow Coma Scale (GCS) and Revised Trauma Score (RTS).

D. Reassessments

1. Assessments will be done according to the following schedule, and contain a minimum of a full set of vital signs. Focused and/or full system reassessments will be repeated based on the clinician's clinical judgment:

a.	ESI 1 – Resuscitation	every 15 minutes
b.	ESI 2 – Emergent	every 60 minutes
c.	ESI 3 – Urgent	every 2 hours
d.	ESI 4 – Non-urgent	as appropriate
e.	ESI 5 – Deferred	as appropriate

2. Reassessment of pain medications will be within 60 minutes of medication administration

3. All treatments and medications will have an appropriate reassessment within an acceptable time frame for that treatment or medication (i.e. urinary output following Lasix administration).

E. Discharge Assessment

1. All patients will have a complete set of vital signs upon final disposition (discharge, admission, or transfer). The exception is if the patient had normal vital signs upon arrival and received disposition less than 60 minutes after arrival.

2. All patients will have their pain assessed upon final discharge.

3. All patients will have a brief discharge summary of their condition and reassessment of any pertinent body systems upon disposition.

REFERENCES:

- Salentiny-Wrobleski, D.M., (2019, September) ENA Position Statement Safe Discharge from the Emergency Department. Retrieved from: https://www.ena.org/docs/default-source/resource-library/practice-resources/position-statements/safedischargefromed.pdf?sfvrsn=998ee45f_10.

- Stone E., Wolf L. (2017, May) ENA Position Statement Triage Qualifications and Competency. Retrieved from : https://www.ena.org/docs/default-source/resource-library/practice-resources/position-statements/triagequalificationscompetency.pdf?sfvrsn=a0bbc268_8.

- Gilboy,N. et al, 2020, Implementation Handbook 2020 Edition ESI Emergency Severity Index v4. Emergency Nurses Association.

SUBJECT:	SECTION:
EQUIPMENT AND SUPPLIES	**Page 1 of 4**

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

PURPOSE:

To ensure all equipment and supplies are available and in working order to provide quality patient care.

AFFECTED PERSONNEL/AREAS:

EMERGENCY DEPARTMENT DIRECTOR/EMERGENCY DEPARTMENT STAFF

PROCEDURE:

Supplies:

1. Each treatment room is stocked with supplies needed to provide patient care. Inventory list is posted to assist in inventory control and stocking. Back up supplies and special items are stocked in the main storage room, core room, and trauma rooms.

2. Routine PAR levels are checked by Materials Management and all missing items are replaced. An accounting is done against the stickers to determine if proper patient charging is done. Urgent requests for items should be called directly to Distribution/Materials Management or to the House Supervisor (after hours) to obtain items needed.

3. All requests for special supplies not stocked by the hospital should be communicated to the Emergency Department management staff.

Equipment:

1. All of the equipment needed for giving care to the Emergency Department patient is kept in the immediate area of the department.

2. Emergency Department equipment that is loaned to other departments must be logged by the charge nurse and equipment must be returned as quickly as possible.

3. If hospital equipment is sent with a patient during their transfer to another facility, the following arrangements should be made with the ambulance company:

    a. If the ambulance company has similar equipment, their equipment should be used if it is not detrimental to patient care.

    b. Arrangements should be made to have the equipment returned. Most facilities maintain a holding area for later pick up. Skull tongs may be exchanged.

    c. Specialized equipment (monitors, pumps, respirators, etc.) are never sent unless accompanied by a knowledgeable member of the hospital staff.

4. Equipment left by ambulance companies, fire departments, and rescue services, which are removed from the patient in the course of treatment, are maintained for pick up by the respective company.

Specialty Trays/Sterilization:

Upon completion of a procedure, the specialty tray (chest tube tray, pericardial tap tray, etc.) will be taken to Central Processing for sterilization. When a tray is taken to Central Processing, an exchange will take place to ensure that the Emergency Department has all the necessary equipment to care for patients. All exchange items will be placed back in their designated spot. If the tray is unique and no replacement is available, Central Processing will be informed so that its sterilization can be expedited.

Crash Cart:

1. The content of the Crash Cart is located in an inventory binder stored on the top of each Crash Cart.

2. A red breakaway lock is placed on the Crash Cart to secure all emergency drugs and equipment. Presence of the secured lock is verified every 12 hours. If the lock is unsecured, the Crash Cart is considered used.

3. When the Crash Cart is used, it needs to be replaced as soon as possible by a secured cart from Central Processing.

    a. **Monday thru Friday from 0700-1500**: Central Processing will be notified and a "cart exchange" will take place. An employee from central processing will bring a fully stocked unused cart to replace the used one.

    b. **Saturday and Sunday and during the hours of 1500-0700**: The house supervisor will exchange the cart.

4. Pharmacy will check all crash cart medication drawers for content, ensuring that all drugs are present and within the expiration date.

5. Each morning, the following items will be checked and documented. The day shift Charge RN will be able to monitor compliance.

    a. **Oxygen tanks**: All E-cylinder tanks are to be checked daily by an Emergency Department certified nurse assistant (CNA). They will be checked for adequacy of content and performance of the regulator. Any problem or refill needs will be referred immediately to the Engineering Department.

    b. **Defibrillators**: Each defibrillator in the Emergency Department will be cycled each morning. **The defibrillator must be disconnected from the electrical wall plug,** and then charged to 30 joules. When charged, the energy is discharged by the nurse. The delivered energy on the screen should match the set amount. If the delivered energy does not match the setting or there is any other problem, Biomed/Engineering Department will be notified immediately and the unit taken out of service. The initials of the staff nurse performing the checks will document that it is complete.

Equipment Failure:

Repair requests are to be entered on the intranet. When any type of maintenance or repair is requested, a request form should be filled out. If the problem is of an urgent nature requiring immediate attention, notify Engineering by paging or telephoning and fill out the request form on the intranet.

1. If the equipment problem is of such a nature that the Engineering Department cannot correct it themselves, they are responsible for contacting the appropriate party and making all arrangements for repair.

2. Major electrical equipment is on the Preventative Maintenance Contract and is routinely checked.

3. If equipment is out of service because of a problem, this should be communicated to all personnel by posting a memo. Arrangements should be made so that service to the patients is not interrupted due to loss of equipment. The Emergency Department Director should be informed of all such occurrences.

4. Each employee is responsible for immediately notifying their immediate supervisor of any equipment malfunction or problem so that it may be dealt with as soon as possible.

Reporting Product Problems

1. Any defective supply or problem with a supply item should be immediately reported to Materials Management.

2. ***The defective item and the wrapper should be saved***. The wrapper has the product's lot number. The item, wrapper, and an occurrence report describing the problem should be routed to the Emergency Department Director for follow-up.

Supplies for outside patients

1. Patient chargeable items should not be given or sold to anyone other than through normal hospital patient use.

   If a patient has a special need for an item which cannot be procured in any other manner:

   a. A patient that is in a life-threatening situation will be registered as an Emergency Department patient and treated appropriately.

   b. If there is no life-threatening situation, the patient should be logged in with a brief description of concern/request.

   c. If the patient refuses to be seen in the Emergency Department, either Risk Management or Administration should be involved, with the intent to remedy the patient's issue.

REFERENCE:

- The Joint Commission (2020). Hospital accreditation standards. Joint Commission Resources. Oak Brook, IL.

SUBJECT: **FENTANYL TRANSDERMAL PATCH USE**	SECTION: ***Drug Protocols*** **Page 1 of 2**

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

PURPOSE:

To define appropriate use for fentanyl transdermal patches as defined by the manufacturer and as required by the FDA.

POLICY:

A. COMPLIANCE – KEY ELEMENTS

1. Opioid analgesic regimens should by tailored to type of pain being treated with consideration for route of administration, degree of tolerance for opioids, age, weight, and medical condition.

2. Fentanyl transdermal patches are indicated for treatment of chronic pain in patients who require continuous opioid administration that cannot be managed with other pain medications (acetaminophen-opioid combinations, NSAIDs, or short-acting opioid analgesics). Serious or life-threatening hypoventilation may occur, even in opioid tolerant patients.

3. Fentanyl transdermal patches are contraindicated in:

   a. The management of acute pain or post-operative pain. This includes outpatient surgeries because there is no opportunity for proper dose titration.

   b. Mild or intermittent pain that is responsive to other therapies.

   c. Patients who are not opioid tolerant (because serious or life-threatening hypoventilation could occur.

   d. Patients less than 2 years of age.

AFFECTED PERSONNEL/AREAS: *ALL PATIENT CARE AREAS*

PROCEDURE:

1. Fentanyl patches will only be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a total daily dose at least equivalent to fentanyl 25 mcg/hr. Patients who are considered opioid tolerant are those who have been taking, for a week or longer, at least 60 mg of oral morphine daily, or at least 30 mg of oral oxycodone daily, or at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid.

2. Fentanyl transdermal patches will not be dispensed prior to discharge if a patient has not been receiving fentanyl transdermal patches during inpatient in the hospital. If a patient has been on a fentanyl transdermal patch in the hospital, it is recommended that the patient receive the same

dose if the patient requires continuation upon transfer to a different facility and/or discharge to home.

3. Orders for fentanyl transdermal patches for outpatient surgery patients will not be allowed.

4. Fentanyl transdermal patches will not be dispensed or be made available to Emergency Department (non-admitted) patients.

References

1. Inappropriate Fentanyl Patch Prescriptions at Discharge for Opioid-Naïve, Elderly Patients. Institute for Safe Medication Practices. July 2, 2020. Accessed June 30th, 2023. https://www.ismp.org/resources/inappropriate-fentanyl-patch-prescriptions-discharge-opioid-naive-elderly-patients

2. Fentanyl. Lexicomp. https://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/6903?cesid=9Giadfb7iCZ&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3DfentaNYL%2Bpatch%26t%3Dname%26acs%3Dtrue%26acq%3Dfentanyl Last updated June 28th, 2023. Accessed June 30th, 2023.

3. FDA. Important information for the safe use of fentanyl transdermal system (patch). Public Health Advisory and Information. July 2005. Contents archived.

4. FDA. Important information for the safe use of fentanyl transdermal system (marketed as Duragesic and generics)—12/21/2007 update. December 21, 2007. Contents archived.

SUBJECT: **GUIDELINES FOR PRODUCT DATING**	SECTION: **Page 1 of 4**

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

GENERAL:

All medications at Sierra View Medical Center (SVMC) will be stored in accordance with the most recent guidelines as established by the United States Pharmacopoeia (USP) and the National Formulary (NF) as well as manufacturer recommendations, and recommendations from the Centers for Disease Control and Prevention (CDC).

PURPOSE:

To define the appropriate use/duration for an agent in order to maintain compliance with the pharmaceutical industry standards.

POLICY:

All medications will be stored in accordance with the manufacturer, USP, or NF guidelines.

AFFECTED AREAS/ PERSONNEL: *PHARMACY, NURSING*

PROCEDURE:

1. Multi-dose vials

    a. All multi-dose medication containers shall display the concentration of the preparation made, dated (with the expiration date, not the date first opened), and initialed when opened.

    b. All multi-dose injectable medication containers will be refrigerated after opening, unless specifically labeled "DO NOT REFRIGERATE"

    c. Inspect prior to each use for suspected or visible contamination. Discard if contamination is suspected.

    d. If a multi-dose vial enters an immediate patient care area, it should be dedicated for single-patient use only.

    e. All multi-dose vials should be discarded after being used for a single patient whenever possible.

2. Warming of irrigation solutions

    a. Once the containers have been removed from the warmer, they should be identified as having been warmed and should not be returned to the warmer. If unopened, the plastic bottles may continue to be used until the manufacturer's expiration date, provided that they have not been warmed more than once.

b. Large volume intravenous (IV) solutions (VIAFLEX plastic containers):

i. IV solutions greater than 150ml may be warmed in their over pouches to temperatures and periods not exceeding:

1. 40°C (104°F) for 14 days

c. Arthromatic and Uromatic Containers:

i. May be warmed in their over pouches to temperatures and periods not exceeding:

1. 45°C (113°F) for 14 days
OR
2. 66°C (150°F) for 72 hours

d. Irrigation solutions in Plastic Pour Bottles:

i. May be warmed to temperatures and periods not exceeding:

1. 66°C (150°F) for 72 hours

2. 50°C (122°F) for 60 days

a. Discard container once removed from warmer

3. Refrigerated IV Solutions

a. Lactated Ringer's and Normal Saline 1000 ml Solutions;
i. 36°F (2°C)-46°F(8°C) for 30 days
ii. May not be returned to room temperature after being refrigerated

SUBJECT: **GUIDELINES FOR PRODUCT DATING**	SECTION: **Page 3 of 4**

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

PRODUCT EXPIRATION DATING

Description	Requires Date & Initials (yes/no)	Expiration Date
Injectables		
Ampules	No	Discard immediately after use. Use filter needles as per policy.
Single Dose Vials (without preservatives)	No	4 hours after initial entry into closed container; 12 hours in ISO Class 5 or cleaner
Multi-Dose Vials (with preservative)	Yes	28 days after opening
Insulin	Yes	28 days after opening
IV Solutions Mixed		
Mixed on unit/Patient care area	Yes	Discard 4 hours after mixing unless stability mandates an earlier expiration
Mixed in pharmacy	Yes	As indicated by the date on the IV label which is determined by the pharmacist
IV Solutions Unmixed		
IV solutions 100 ml or over	Yes	28 days after protective wrap removal
IV solutions less than 100 ml	Yes	15 days after protective wrap removal
Mini-Bag Plus VIAFLEX Containers		
5% Dextrose Injection, 50 & 100mL MINI-BAG Plus Container Single Pack	No	Use Immediately (Up to 24hrs)-if prepared in pharmacy date & initials required on label
0.9% Sodium Chloride, 50 & 100mL MINI-BAG Plus Container Single Pack	No	Use Immediately (Up to 24hrs)- if prepared in pharmacy date & initials required on label
Irrigation solutions		
Saline or Sterile Water	Yes	Discard 24 hours after opening
EENT solutions- nasal, otic, ophthalmic	Yes	Discard one year after opening or manufacturer's expiration date- whichever comes first
Oral Medications		
Liquids - elixirs, solutions, suspensions, syrups, solids	Yes	Discard 1 year after opening or manufacturer's expiration date- whichever comes first
Nitroglycerin tablets	Yes	Discard 6 months after opening
Topicals		
Solutions, ointments, creams, etc.	Yes	Discard 1 year after opening or manufacturer's expiration date- whichever comes first
Antiseptics – Alcohol, Betadine, Hibiclens, Phisohex	Yes	Discard 1 year after opening or manufacturer's expiration date- whichever

		comes first

REFERENCES:

- "Revised USP Standards for Product Dating, Packaging, and Temperature Monitoring," Am J Health-System Pharmacy Volume 57, Aug 1, 2000: 1441-1445.
- USP 797.(n.d.). Retrieved November 30, 2022 from http://www.usp.org/compounding/general-chapter-797.
- USP/NF<695>Packaging and Storage Requirements. Retrieved November 30, 2022 from https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/659_rb_notice.pdf.
- Medical Information Letter from Baxter Healthcare Corporation. Received December 17th, 2021.

SUBJECT: **IV PREPARATION AND DISPENSING**	SECTION: ***Pharmaceutical Services*** **Page 1 of 14**

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

PURPOSE:

To provide guidelines to ensure quality sterile compound products are produced by using consistent validated methods.

DEFINITION:

Designated Persons- The pharmacist in charge and the IV sterile product lead technician will serve as the designated persons who are assigned to be accountable and responsible for the operation and performance of the compounding facility and personnel.

PEC-Primary Engineering Control- A device that provides an International Organization for Standardization (ISO) Class 5 or better environment through the use of non-turbulent, unidirectional high efficiency particulate air (HEPA)-filtered first air for compounding sterile preparations.

Segregated Compounding Area (SCA)- A designated space for sterile-to-sterile compounding where a PEC is located.

Aseptic Processing/Preparation- The technique involving procedures designed to preclude contamination (of drugs, packaging, equipment, or supplies) by microorganisms during processing.

ISO Class 5 Environment- One that contains no more than 3,520 particles per cubic meter that are 0.5 microns or larger in size.

Vertical Laminar Airflow Hoods- A device used to achieve the ISO Class 5 environment that sweeps filtered air from top to bottom.

CAI- Compounding Aseptic Isolator- A unidirectional HEPA-filtered airflow isolator that creates a positive pressure controlled environment. It is designed to provide worker protection from exposure to undesirable levels of airborne drug and to provide an aseptic environment for compounding sterile preparations.

CACI- Compounding Aseptic Containment Isolator- A unidirectional HEPA-filtered airflow isolator that creates a negative pressure controlled environment. It is designed to provide worker protection from exposure to undesirable levels of airborne drug and to provide an aseptic environment for compounding sterile preparations.

High-Efficiency Particulate Air (HEPA) filter - A filter composed of pleats of filter medium separated by rigid sheets of corrugated paper or aluminum foil that direct parallel flow that removes air particles 0.3 micrometers or larger.

CSP- Compounded sterile preparation

Critical Site – Any direct pathway through which contaminants may enter a sterile product (e.g. the point at which a needle pierces a vial stopper).

First Air – First air is the uninterrupted flow of air from the HEPA filter.

Beyond use date (BUD) – Beyond Use Date is the date and hour after which a CSP must not be used.

In-Use Time –The time before which a conventionally manufactured product or a CSP must be used after it has been opened or needle punctured (e.g. after a container closure of a vial has been penetrated). It cannot exceed the BUD or the manufacturer's expiration date.

Category 1 Compounded Sterile Product (CSP)- Category 1 is a risk-based approach defined in USP 797 that establishes a specific BUD for products, personnel qualifications, environmental monitoring, release testing required for sterile compounding. It assigns a BUD of 12 hours at room temperature and 24 hours refrigerated. SVMC BUD for products made in the main hospital pharmacy will not exceed 12 hours.

Category 2 Compounded Sterile Product (CSP)- Category 2 is a risk-based approach defined in USP 797 that establishes a specific BUD for products, personnel qualifications, environmental monitoring, release testing required for sterile compounding. It assigns a BUD of greater than 12 hours at room temperature or greater than 24 hours when refrigerated.

POLICY STATEMENT:

It is the policy of Sierra View Medical Center (SVMC) that sterile pharmaceutical products will be prepared using accepted standards of practice.

PROCEDURE:

A. Sterile compounded products must be made in pharmacy in an ISO Class 5 PEC environment.

   a. Sterile compounded products may be made outside of an ISO Class 5 environment only in the case of an emergency where waiting could result in harm to a patient.

      i. These preparations shall be labeled "for immediate use only" and administration shall begin no later than four hours following the start of the compounding process.

      ii. Unless the immediate use preparation is immediately and completely administered by the person who prepares it or is witnessed by the preparer, then the preparation shall bear a label with the following information:

         1. Patient identification unless preparation is done at patient's bedside
         2. Names and amounts of all ingredients, may not exceed three ingredients.

3. Name or initials of person preparing it
4. Exact four (4) hour beyond use date and time
5. If administration has not begun within the four (4) hours, then the preparation will be discarded.
6. Any unused source containers with residual drug shall be properly discarded.

iii. The segregated compounding area in the main hospital pharmacy provides ONLY category 1 sterile-to-sterile preparations.

b. All active and inactive ingredients used in sterile compounding at SVMC shall be procured from a supplier registered with the Food and Drug Administration (FDA).

c. Category 1 or 2 CSP's may be prepared at SVMC's Cancer Treatment Center's Suite B nonhazardous sterile product IV room.

B. Master Formulation Records must be present before the pharmacy can compound any sterile preparations. They must contain the following elements:

a. Name, strength, dosage form

b. Quantity prepared

c. Active ingredients and amounts

d. Inactive ingredients and amounts

e. Equipment to be used

f. The maximum allowable beyond use date for the preparation and the rationale or reference source justifying its determination.

g. Sierra View Medical Center's main pharmacy has a maximum BUD per USP 797's Category 1 specifications.

h. Sierra View's Cancer Treatment Suite B is a nonhazardous product room is a Category 2 facility. The maximum BUD will not exceed 8 days for refrigerated items.

i. Specific and essential compounding steps used to prepare the drug.

j. Quality reviews required at each step in the preparation of the drug.

k. Post-compounding process and any required post-compounding process and procedures, qualitative checks, including visual check and pharmacist initials that signify final product check.

l. Instructions for storage and handling of the compounded drug preparation.

m. Physical description of final preparation and final container to be used.

n. Where the pharmacy does not routinely compound a preparation, then the record may be documented on the prescription itself.

o. Any other information that may be needed to describe the operation and ensure its reproducibility.

p. Professional reference to cite where the compounding information can be found.

C. The methodology for determining the formulation of the sterile product shall be:

a. Consulting appropriate professional references

i. USP 797
ii. American Society of Health System Pharmacist
iii. Trissel's Drug Compatibility
iv. Lexi Comp Drug Information
v. Drug manufacturer package insert

D. A Compounding Record will be present and contain all of the following elements:

a. Name, strength, and dosage form of the compounded sterile preparation

b. Date and time that the preparation was compounded

c. Identity of pharmacy technician and pharmacist who performed the PRE check and POST compounding check.

d. Name and amount of each component

e. Manufacturer, expiration date, and lot number of each component

f. A pharmacy assigned unique reference or lot number

g. BUD: SVMC main pharmacy (Category 1) and CTC Suite B (Category 2)

h. The final quantity or amount of drug preparation compounded for dispensing

i. Visual check of final product.

j. Master formula recorded as reference.

k. The log will be separated alphabetically by active ingredient. All logs will be kept for three years and will be filed alphabetically by the active ingredient's generic name. The last year's compounded drugs will be kept in the pharmacy. Any previous years will be kept at a designated pharmacy storage site as per approved Board of Pharmacy waiver to store records off site.

E. The most common source of contamination of sterile products is from personnel. The two most common causes of these contaminations are via particle shedding from personnel and improper manipulation of equipment.

a. Contamination from personnel due to shedding can be reduced by proper hand hygiene, gowning and gloving.

i. Personnel who are experiencing rashes, sunburn, weeping sores, conjunctivitis, or active respiratory infections shall not compound sterile products.

F. Compounding personnel shall not wear cosmetics, hand, wrist, or other visible jewelry, artificial nails, or extenders. Natural nails shall be kept neat and trimmed. Do not wear earbuds or headphones. Do not bring unnecessary electronic devices into the compounding area. Wipe eyeglasses, if worn.

G. Hand hygiene and donning of personal protective equipment (PPE) will take place in the anteroom:

a. Shoe covers.

b. Hair/beard cover should contain all hair.

c. Mask should be worn to cover from bridge of nose to chin.

d. Hands and forearms will be vigorously washed with soap (and water for at least 30 seconds.

- Remove debris from under fingernails, if present, using a nail cleaner (pick) under warm water.

- Hands and forearms shall be washed vigorously with soap and water for at least 30 seconds.

- Dry hands and forearms up to the elbows with low-lint disposable towels.
- A clean non-shedding gown dedicated to use in the compounding area shall be donned. Gowns that are open (tied) in the back are to be utilized.
- Prior to donning sterile gloves, use Sterillium© and allow hands to dry thoroughly.
- Put on appropriate sized sterile gloves and apply sterile 70% alcohol and allow to dry.

e. Gloves should be disinfected immediately before compounding begins, before inserting hands into CAI, and before entering or re-entering the PEC and after contact with non-sterile objects.

f. Gloves that become contaminated by contact with non-sterile surfaces should be disinfected with sterile 70% isopropyl.

g. Gloves should be changed whenever contaminated (spills, etc.), torn or every 30 minutes.

h. The CAI fixed glove assembly shall don sterile gloves OVER the CAI isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again or when a rip or tear is visible.

H. Personnel will not prepare compounded sterile products until training is complete and competency validated as per SVMC policy STERILE PRODUCTS:EDUCATION AND COMPETENCY.

a. Personnel will be validated every 6 months for garbing competency (including GFT) and media fill with post-GFT and surface sampling. Furthermore, they will be validated every 12 months for training and competency in sterile compounding principles and practices. There will be dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

b. Periodic quality checks will be performed per policy. Failure of any quality test will result in the employee being unable to compound sterile products until retrained and competency validated.

I. Proper conduct in the sterile processing area also protects from contamination.

a. Food and drink are prohibited in all areas of the SCA or cleanroom.

b. Actions such as talking and coughing should be directed away from the work area.

c. Any unnecessary motion within the hood should be avoided to minimize the turbulence of air flow.

d. Activities in the sterile products room should only be related to the procedures for parenteral preparations.

e. No cardboard boxes may be in the ante-room or segregated compounding area. Supplies shall be wiped down with sterile alcohol before placing them in the anteroom and buffer room.

J. Proper technique in the ISO Class 5 environment is required to prevent contamination.

a. The critical principle in using laminar airflow hoods is that nothing should interrupt the flow of air between the HEPA filter and the critical site.

b. To maintain sterility, nothing should pass behind a sterile object in a vertical flow hood. Materials placed within the laminar flow hood disturb the patterned flow of air blowing from the HEPA filter. When laminar air flow is moving on all sides of an object, the zone of turbulence is created that may extend six times the diameter of the object. For these reasons, it is advisable to work with objects at least six inches from the sides and front of the hood without blocking air vents, so that unobstructed airflow is maintained between the HEPA filter and sterile objects.

c. Overcrowding of the critical work area may interfere with airflow and increase the potential for compounding errors. Only one individual may work in a hood at one time.

d. Items introduced into the CAI/Hood and their critical sites (vial stopper, IV bag septum) or hood shall be disinfected with 70% sterile alcohol and allowed to dry before aseptic manipulations begin.

K. Although the laminar air flow hood provides an aseptic environment that is safe for the manipulation of sterile products, it is essential that strict aseptic technique be used in conjunction with proper hood preparation.

L. All equipment (syringes, needles, bags, devices) will be used according to standard references to ensure quality, stability and compatibility. Up-to-date references are available in the pharmacy.

M. Ampule Use

a. Before an ampule is opened, any solution visible in the top portion (head) should be moved to the bottom (body) by swirling the ampule in an upright position.

b. To make an ampule break properly, the ampule neck is cleansed with an alcohol swab and the swab should be left in place. Pressure should be exerted on both thumbs, pushing away from oneself in a quick motion to snap open the ampule.

c. Ampules should not be opened toward the HEPA filter of the laminar flow hood or toward other sterile products within the hood.

d. To withdraw medication from an ampule, the ampule should be tilted and the bevel of the needle placed in the corner space (or shoulder) near the opening. As fluid is withdrawn, increase the angle of tilt so that more of the ampule contents flows into the shoulder.

e. Use a filter needle or filter straw to withdraw the ampule contents, and then switch to a regular needle before expelling the solution from the syringe. Alternatively, a regular needle may be used to draw the solution from the ampule, but a filter needle must be used when expelling the solution from the syringe.

f. All ampules are to be immediately discarded and are not to be stored for any length of time.

N. Vial Use

a. Vials with drugs in solution can be multi dose or single dose.

b. Multi dose vials contain a small amount of preservative agent. The presence of these substances does not make the solution self-sterilizing and the use of strict aseptic technique is still required. Common substances used as preservatives include benzyl alcohol, parabens, phenol and benzalkonium chloride. Due to their toxicity, solutions with preservatives should not be used in preparations for pediatric or neonatal patients or for epidural or intrathecal dosage forms.

c. Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications is used in its entirety or its remaining contents are labeled with a BUD and discarded within 28 days from initial opening or puncture. Any multidose container not stored properly or not labeled with a BUD or if BUD is incorrect, the container and drug must be immediately discarded.

d. Single-dose vials do not contain preservative.

i. Most protective covers do not guarantee sterility of the rubber stopper. Before the stopper is penetrated, it must be swabbed with 70% isopropyl alcohol and allowed to dry.

ii. Needle entry into vials with rubber stoppers should be done cautiously to avoid the creation of rubber core particles.

d. Single-dose containers of a compounded sterile drug preparation, other than an ampule, such as a bag, bottle, syringe, or vial, are used in their entirety or their remaining contents are to be labeled with a BUD and discarded within the following time limit, depending on the environment:

i. When needle-punctured in an environment with air quality worse than ISO Class 5,will be discarded after four hours.
ii. When needle-punctured in an environment with ISO Class 5 or better air quality, within twelve hours, unless otherwise specified by the manufacturer.

O. The Role of the Pharmacist

a. As physician's orders are received, the pharmacist will enter the order into the computer, preferably selecting premixed preparations.

b. Medications not available in premixed form will be entered in the computer as part of a multiple item compound that includes the appropriate volume of a compatible base solution.

c. A label will be generated from the computer system.

d. The pharmacist will check ALL ingredients (and calculations) prior to a pharmacy technician commencing any compounding. This PRE check will be documented on the compounding log.

e. Upon completion of the compounding, the pharmacist will visually inspect the product for visible turbidity, cloudiness, i.e., qualitative inspection of the final product and document this on the compounding log, a POST Check.

P. The Role of the Pharmacy Technician

a. Disposal of Supplies Upon Completion of Sterile Compounding

i. Needles will be discarded in puncture-resistant, sealable containers, often called "sharp" containers.
ii. Do NOT recap needles before discarding them into the "sharps" container.
iii. Syringes and containers that do not have medication in them that is not considered to be Resource Conservation and Recovery Act (RCRA) waste shall be disposed of in appropriate pharmaceutical waste bins.
iv. Nonhazardous, empty vials may be discarded in the regular trash.

b. Intravenous Piggyback Set-Up Procedures

i. An intravenous admixture ward list will be printed once a day by pharmacy technicians. This list will create intravenous admixture labels that will need to be affixed to either premixed (from the manufacturer) admixtures. If there are no premixed solutions available, then the admixture will be compounded in the compounding aseptic isolator.
ii. Any frozen solutions shall be thawed from the Pharmacy service freezer.
iii. Using the oldest frozen preparation that will not expire within the 24-hour dispensing period, the technician will label each solution specifically for the patient, drug, and dose.
iv. Expiration dates on the frozen solutions will be checked to assure the oldest acceptable date.
v. Docking of proprietary bag to vial systems for future activation must be done in accordance with USP 797 in an ISO Class 5 environment.

c. Pediatric Syringe Preparation Procedure

i. The intravenous admixture ward list will be printed once a day.
ii. Patients with doses due before the next list is printed will have those labels segregated from the worklist.
iii. The amount of drug needed for compounding based on total patient requirements shall be determined.
iv. Materials required for aseptic medication transfer should be gathered and placed in the CAI antechamber and wiped with sterile alcohol.
v. The supplies and drug shall be transferred into the CAI mixing chamber and allowed to sit undisturbed for at least three minutes to allow for the CAI to purge any airborne particles.
vi. The technician will call the pharmacist into the IV room for a PRE check on the materials and calculations for the preparation to be compounded. The identity and quantity of each component will be validated by the pharmacist BEFORE the addition is performed.
vii. After the pharmacist signs off on the PRE check on the compounding log, the appropriate amount of medication for syringe preparation shall be diluted (in the CAI) by the technician.
viii. The calculated amount of drug shall be drawn into the syringe.
ix. Aseptically, the technician will inject the syringe contents into the predetermined base solution and affix the patient-specific label.
x. The patient-specific label is immediately applied and the product is removed from the CAI and made available for the pharmacist to do a final quality check.
xi. The remaining drug in the source container shall be discarded.

d. Large volume parenteral preparation procedure:

i. Solution fill list and labels are obtained as described in the pediatric syringe preparation.

ii. Labels are assembled according to additive type.

iii. The outer wraps of solutions are removed upon reintroduction into the PEC. The large volume bags are wiped with sterile alcohol in the CAI antechamber.

iv. The materials for compounding (drugs and syringes, etc.) are placed in the mixing chamber in the CAI and allowed to sit for a minimum of three (3) minutes to allow for the particulate to return to an ISO class 5 state.

v. The pharmacist is called into the IV room, and the identity, quantity, and calculations are reviewed with the technician prior to the pharmacist signing the compounding log and prior to the technician compounding the sterile product.

vi. The patient specific label is immediately applied and the product is removed from the CAI and made available for the pharmacist to do a final quality check.

Q. Sterile product preparation and verification PRE procedure to be done by the technician BEFORE and during the pharmacist's PRE compounding check:

a. Drugs and equipment and patient specific label (needles/syringes/alcohol wipes/etc.) necessary to prepare and mixture will be assembled for the pharmacist to review with the technician.

b. Ingredients will be carefully checked for accuracy using the master formulation record and label. All products selected for use in compounding shall be verified by the pharmacist prior to any compounding activity. In addition, calculations will be verified with the pharmacist during the PRE CHECK phase of compounding.

c. The pharmacist will then sign and date the compounding log acknowledging the technician has assembled all proper materials, drugs, equipment and has reviewed any and all pertinent calculations.

R. Procedure for transferring necessary ingredients and equipment into the PEC. All items will be carefully wiped down with sterile alcohol and allowed to dry before being placed in the PEC.

a. Only ingredients to make one admixture should be in the PEC.

b. Items will be arranged in a manner that does not block or disrupt airflow.

c. After the compounding materials are in the PEC, a purge time of three (3) minutes will pass before beginning any compounding activities.

d. Gloves will be disinfected with sterile alcohol and allowed to dry.

e. A pharmacist will check ingredients and calculations prior to compounding.

f. Admixture will be prepared using aseptic technique.

g. Trash will be managed in a way that does not obstruct airflow.

h. Admixture will be removed from the PEC and labeled.

i. Label will be signed by the employee and the beyond use date will be written on the label.

j. Employee preparing and pharmacist checking the IV will inspect the IV for leakage, foreign matter, precipitate, or cloudiness.

k. All ingredients and supplies will be removed from PEC and kept together for verification by a pharmacist.

S. Sterile product labels must contain the following elements:

a. The generic names of the drugs

b. The quantity or volume and strength of the active ingredient(s)

c. The name of the patient

d. The direction for use

e. The date of dispensing

f. The name and address of the compounding pharmacy and dispensing pharmacy if different.

g. An order number to identify the prescription, e.g., lot number or pharmacy reference number (prescription number).

h. The name of the prescriber

i. Beyond Use Date (BUD)

j. Date compounded

k. Route of administration

l. Rate of administration for IV admixtures

m. Instructions for storage & handling or warning labels if needed

n. All hazardous drugs shall bear a label which states, "Chemotherapy-Dispose of Properly" or "Hazardous-Dispose of Properly"

T. Statement the "Drug was compounded in pharmacy" if preparation was not outsourced.

U. Beyond Use Dating (BUD) will be assigned to all drug products based on manufacturer's chemical stability recommendations or in accordance with the standards for sterility testing found in USP 797, whichever is shorter.

a. SVMC's main pharmacy exclusively prepares sterile-to-sterile transfers in an ISO class 5 PEC that is located in a segregated compounding area, i.e., Category 1 classification.

b. The Cancer Treatment Center (CTC) suite B prepares hazardous and non-hazardous compounded sterile products by using sterile to sterile transfers in a negative pressure hood and room and a positive pressure room and hood, respectively. The products produced at this location will qualify for Category 2 and MAY have a BUD of not greater than 4 days at room temperature and 10 days refrigerated.

U. Single-dose and multi-dose container dating

a. A single-dose container (not an ampule) must be used entirely or discarded:

i. Within twelve hours, if needle-punctured or opened in an ISO Class 5 environment. If a puncture time is not noted on the container, the container must be immediately discarded.

ii. Within four hours, if needle-punctured or opened in a worse than ISO Class 5 environment.

b. An ampule is a single-dose container that must be used immediately and not stored for any timeframe.

c. A multi-dose container must be used or discarded within 28 days (or shorter if specified by manufacturer).

V. Documentation Retention

a. All records of compounding and materials used to compound sterile preparations shall be maintained in a readily retrievable form for three (3) years from the date the record was last in effect. They will be maintained in a manner to provide an audit trail for revisions and updates of each record document. Any change shall be documented by

b. The pharmacy will maintain records of the acquisition, storage, and destruction of any component used in compounding.

W. Whenever a change in a policy or procedure occurs, the pharmacist in charge will notify the staff via a meeting or email. Staff shall sign off on changes acknowledging changes and intent to comply. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action by the Board of Pharmacy.

X. This policy and all policies related to sterile compounding will be reviewed annually by the pharmacist-in-charge, and recordation of the annual review shall be present on each policy and be readily retrievable upon request by the Board of Pharmacy.

Y. All pharmacy staff who compound sterile products or who are responsible for training staff who work in the sterile product environment shall review all policies related to sterile products annually. Documentation of the annual staff review shall be readily retrievable for the State Board of Pharmacy.

Z. In the event of a drug recall, the written plan found in DRUG RECALL PROCEDURE shall be followed.

AA. The Department of Pharmacy will not handle or compound any infectious materials in the sterile compounding area.

EDUCATION:

SVMC Staff: All pharmacist and pharmacy technicians will receive education regarding sterile product preparation and aseptic technique.

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SUBJECT: **INFILTRATE MANAGEMENT**	SECTION: **Page 1 of 8**

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

PURPOSE:

This document directs the registered nurse (RN) in the management of peripheral IV infiltrations, outlining administration as ordered by the physician, of hyaluronidase for severe (Stage III and IV) infiltrations and phentolamine for infiltration of vasoactive medications.

POLICY:

The stage of infiltration, the nature of the infiltrated fluids and the availability of specific antidotes determine the degree of intervention. IV infiltration or extravasations of known vesicants are managed according to the guidelines as written.

Extravasation Treatment

Antidote and compress treatment of IV infiltrates and extravasations vary according to the medication extravasated. The RN should follow the Appendix below or the most recent version from Lexicomp online, search of "extravasation". Additional information may be obtained by consulting with the Pharmacist. Measures will be taken to mitigate pain associated with injection procedures.

Definitions

Infiltration: When a non-vesicant fluid leaks from a vein.

Extravasation: The inadvertent leakage or escape of a vesicant drug or solution into healthy tissue.

Vesicant: When the fluid/medication is toxic to the tissue causing blistering and/or necrosis.

AFFECTED AREAS/ PERSONNEL: *NURSING AND PHARMACY*

PROCEDURE:

A. **Assessment**

1. At the very first sign or symptom of infiltration or extravasation, immediately stop the infusion or injection.
2. Estimate the volume of infiltrated fluid and/or medications.
3. Assess motion, sensation, and capillary refill distal to the injury.
4. Consider transferring the patient to a higher level of care based on the severity of the infiltration and frequency of monitoring.

B. **Management**

1. Disconnect the administration set from the catheter hub/IV device. Do not flush the line, and avoid applying pressure to the site.

2. Attach an empty 3- or 5-mL syringe and attempt aspiration of the residual solution/drug from the IV device.

3. For a short peripheral catheter:

   a. For peripheral sites (Peripheral cannula, midline) and peripherally inserted central catheters, elevate the affected extremity.

   b. Remove the dressing and withdraw the catheter.

   c. Use a dry gauze pad to control bleeding.

   d. Apply a dry dressing to the puncture site, but avoid applying excessive pressure on the area.

   e. Do not insert a new peripheral IV catheter distal to a site of infiltration or extravasation.

4. For a central venous catheter:

   a. Clamp the catheter. Consult the physician about the need for a radiographic study of the catheter to determine the cause of the infiltration or extravasation.

   b. Assess the need for continuing IV therapy and plans for another central venous catheter.

5. Evaluation of the need for continuing IV therapy and plans for another central venous catheter.

6. Local thermal treatments are used to decrease the site reaction and absorption of the infiltrate.

   a. Local cooling aids in vasoconstriction to limit drug dispersion.

   b. Local warming (dry heat), aids in vasodilation to enhance dispersion of the vesicant agent and decrease drug accumulation in local tissue.

   c. Refer to Appendix A for guidelines on the use of heat and cold for specific vesicant agents.

   d. Reapply compresses for 15 to 30 minutes every 4-6 hours for 24 to 48 hours.

Note: Heat and cold applications are not well supported in neonates and young infants.

7. Administer the antidote, as ordered by a physician. See procedures below for specific antidote administration.

C. **Procedure for Hyaluronidase (Vitrase) Administration**
Equipment

1. Hyaluronidase 150 units/1 ml vial
2. TB syringe
3. Four to ten ½ inch 30 G needles to minimize pain with injections
4. Appropriate sized blood pressure cuff

a. Process

i. Obtain a physician order for hyaluronidase and order from Pharmacy **STAT**. **Hyaluronidase requires refrigeration until use.**

Key Point: Recommended dose is 1mL (150 units) infiltrated subcutaneously, as five separate injections of 0.2 mL each, into the extravasated site along the leading edge of erythema using a 25 gauge or smaller needle.

ii. Check the physician order prior to the use of the medication.

Local administration: Using a 150 units/mL concentration, mix 0.1 mL (of 150 units/mL) with 0.9 mL NS in 1 mL syringe to make final concentration of 15 units/mL; administer a total of 1 to 1.7 mL (15 units/mL) as 5 separate 0.2 to 0.3 mL (15 units/mL) into area of extravasation

Key Point: Over dosage may cause hypotension.

iii. Cleanse the site with alcohol if skin is intact; if skin is broken or blistered, cleanse with normal saline.

Key Point: Use gentle cleansing, avoiding pressure at site.

iv. Begin subcutaneous injections of hyaluronidase using 0.2ml aliquots. Inject around the infiltrate on the margin of the infiltrate.

Key Point: Change needle after each injection; a maximum of 10 injection sites may be used.

v. Observe the site carefully every fifteen (15) minutes for two (2) hours for improvement in color, capillary refill, skin temperature, and/or edema/swelling.

Key Point: Usually there is a marked decrease in swelling within 15-30 minutes after administration of the enzyme.

vi. **Safety Point: Monitor heart rate and blood pressure carefully and document every 30 minutes times two.** Allergic (urticara) and anaphylactic like reactions may occur. This drug MAY cause hypotension.

vii. Continue to monitor the site for 48 hours after treatment/catheter removal for additional complications.

viii. Implement topical wound care and/or obtain wound care consult per physician orders.

D. **Safety**

1. Verify with a second RN/LVN.
   a. Correct dilution
   b. Reconstitution dosage
2. Overdose / Symptoms of Toxicity
   a. Local edema or urticaria
   b. Erythema
   c. Chills
   d. Nausea/vomiting
   e. Tachycardia
   f. Hypotension
   g. Dizziness

E. **Procedure for Phentolamine (Regitine) Administration**
Equipment

1. 5 mg vial of phentolamine
2. 10 mL syringe
3. Filter needle

4. TB syringe

5. Four to ten ½ inch 30G needles

6. Appropriate-sized blood pressure cuff

a. **Process**

i. Obtain a physician order for phentolamine of 5 to 10mg.
ii. Obtain phentolamine from Pharmacy and double check the order.

iii. Mix 10 mL of 0.9% sodium chloride (normal saline) with each 5 mg vial of phentolamine powder (0.5 mg/ml).

iv. Draw up 1 ml of phentolamine solution (in a TB syringe with a filter needle), remove filter needle and attach a 30 gauge needle for drug administration.

v. Ensure baseline vital signs have been obtained, and then provide continuous blood pressure monitoring (non-invasive blood pressure (NIBP) or arterial blood pressure to repeat every 3 - 5 minutes) throughout administration procedure. If possible, use the extremity that is unaffected by the infiltration for the NIBP.

Note: Phentolamine administration can cause hypotension.

vi. Cleanse site with alcohol if skin is intact; if skin is broken or blistered, cleanse with sterile normal saline.

Key Point: Use gentle cleansing, avoiding pressure at site.

vii. Begin subcutaneous (SQ) injections of phentolamine using 0.1 ml aliquots. Begin at the center of the affected area and work outward, infiltrating the area in a circular pattern. Aspirate syringes frequently to check for blood.

Safety Point: Do not administer phentolamine if blood is aspirated.

Key Point: Obtain a new syringe if blood is aspirated.

Key Point: Change the needle after each injection.

viii. Continue administering the diluted solution as long as the patient's vital signs are stable, until the entire area is re-perfused, or up to the maximum dose of 2.5 mg of diluted phentolamine is given.

Key Point: Take care not to cause so much swelling that a compartment syndrome occurs.

ix. Observe the site carefully every fifteen (15) minutes for two hours for improvement in color, capillary refill, skin temperature, and/or edema/swelling.

x. **Monitor heart rate** (for tachycardia and/or arrhythmias) **and blood pressure carefully and document every 30 minutes times two.**

Safety Point: This drug MAY cause hypotension.

xi. Continue to monitor site for 48 hours after treatment/catheter removal for additional complications.

F. **Reportable Conditions**

If any of the following conditions are noted, discontinue the treatment, notify the physician, and initiate supportive measures immediately per physician orders:

1. Development of hypotension.
2. Development of tachycardia or arrhythmias.
3. Reperfusion of extravasation site does not occur within 30 minutes of completion of administration.

G. **Education**

Teaching is provided regarding indications for antidote administration and potential complications from treatment.

H. **Documentation**

1. Call to physician and orders received.
2. Location of infiltrate/extravasation and type of fluid infiltrated.
3. Appearance of infiltrate/extravasation before intervention – size and color; grade/severity of infiltration/extravasation.
4. Appearance of infiltrate after intervention –size and color.
5. The type, size and length of the catheter involved.

6. Initial interventions e.g. aspiration, catheter removal, application of heat or cold.
7. Total amount of antidote administered.
8. Patient tolerance of procedure.
9. Patient response to interventions.
10. Patient/parent education regarding the event and follow-up care.
11. Vital signs.
12. Complete online event reporting.

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APPENDIX A

Medication Extravasated	Cold/Warm Pack	Antidote

For additional information, search George Page *Policies and documents for Extravasation* or call Pharmacy.

Chemotherapeutic agents

Anthracyclines

Daunorubincin Doxorubincin Mitomycin	Cold	DMSO
Vinblastine Vincristine Vindesine Alkylating agents	Warm	Hyaluronidase (Vitrase)
Mechlorethamine (Nitrogen mustard) Bendamustine Carboplatin Cisplatin Dacarbazine	Cold	Sodium thiosulfate 1/6 molar solution: Inject 2 mL of the 1/6 Molar solution for each mg suspected to have extravasated.
Vasopressors Dopamine Epinephrine Norepinephrine Phenylephrine	None	Phentolamine (Regitine®)
I.V. fluids and other medications Other agents	Cold	

SUBJECT: **IRON DEXTRAN**	SECTION: **Page 1 of 3**

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

PURPOSE:

Provide guidance on intravenous (IV) Iron Dextran infusions, to improve safety & efficacy of infusions.

POLICY:

Consistent treatment of iron deficiency will help decrease the possibility for further complications and provide safe recommendations for those treatments.

AFFECTED PERSONNEL/AREAS: *PHARMACY/NURSING*

PROCEDURE:

APPROPRIATE USE:

[US Boxed Warning]: Use iron dextran only in patients where clinical and laboratory evidence has established the iron deficient state and is not amenable to oral iron therapy. Discontinue oral iron prior to initiating parenteral iron therapy.

Anaphylactic-type reactions, including fatalities, have followed the parenteral administration of iron dextran injection. Have resuscitation equipment and personnel trained in the detection and treatment of anaphylactic-type reactions readily available during iron dextran administration.

PREMEDICATION:

Routine premedication is not given to patients without a history of asthma, active inflammatory bowel disease, or more than one drug allergy.

For patients with asthma or more than one drug allergy, the ordering provider may consider premedication with 125mg of methylprednisolone and 10 mg of famotidine given IV prior to administration of any IV iron product.

TEST DOSE

A test dose (25mg) should be administered on the first day of therapy; observe for at least 1 hour for hypersensitivity reaction, then administer the remainder of the day's therapeutic dose (dose minus test dose). Resuscitation equipment, medication, and trained personnel should be available. An uneventful test dose does not ensure an anaphylactic-type reaction will not occur during administration of the therapeutic dose.

INDICATIONS & DOSING

Low molecular weight Iron Dextran can also be given as a single, total dose infusion; this practice has been shown to be safe and effective in the settings of heavy uterine bleeding, pregnancy, postpartum,

inflammatory bowel disease, gastric bypass, hereditary hemorrhagic telangiectasia, chronic kidney disease, and restless legs syndrome.

Maximum total doses shall not exceed 1000 mg of elemental iron, as they have been deemed to not be clinically useful. A fixed dose of approximately 1000mg is generally sufficient & can provide patient with iron for storage without causing overload.

In this approach, 1000mg would be diluted in 250mL of normal saline and administered over 1 hour. This method is preferred over multiple low dose infusions due to limiting multiple IV placements, costs, possibility of reactions. Again, for a patient's first dose of medication, a test dose would be required & the remainder of the 1000mg could be administered over the balance of 1 hour.

1. Iron-deficiency anemia:

   1* Total dose (mL) = (0.0442 × {desired hemoglobin [g/dL] − observed hemoglobin [g/dL]} × IBW [kg]) + (0.26 × IBW [kg])
   2* IBW = Ideal body weight in kg; if actual body weight is less than IBW, use actual body weight.

2. Total dose infusion (off label): Data from a retrospective analysis suggest that a total dose infusion of iron dextran 1,000 mg over 1 hour is safe and effective in patients with iron deficiency anemia.

3. Iron replacement therapy for blood loss:

   Replacement iron (mg) = blood loss (mL) x Hct

ADMINISTRATION: For all first time treatments with Iron Dextran, see section for test dose.

IM: Use Z-track technique (displacement of the skin laterally prior to injection); injection should be deep into the upper outer quadrant of buttock; alternate buttocks with subsequent injections. Administer test dose at same recommended site using the same technique.

IV: For all first time treatments with Iron Dextran, see section for test dose. An IV test dose should be administered slowly over at least 30 seconds to 5 minutes. Subsequent doses may be administered undiluted at a slow gradual rate not to exceed 50mg/minute (Maximum 100mg).

Total dose infusion (off-label administration):
A retrospective analysis in patients with iron deficiency anemia suggests that a total dose infusion of 1,000 mg (diluted in 250 mL of NS) over 1 hour (after an initial test dose) is safe and effective. Another retrospective analysis in patients with chronic kidney disease and iron deficiency anemia administered the total dose (after the initial test dose) over 4 to 6 hours.

SPECIAL CONSIDERATIONS

- Pregnancy

  Intravenous iron is not given during the first trimester but can be started after 13 to 14 weeks.

PATIENT EDUCATION

1. Inform the patient what the drug is used for.
2. Frequently reported side effects, as listed below.

ADVERSE EFFECTS

- Pain and brown staining at injection site
- Flushing
- Hypotension
- Fever/Chills
- Myalgia
- Anaphylaxis or Wheezing
- Chest tightness
- Fever
- Itching or Swelling face/lips/tongue/throat

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SUBJECT:	SECTION:
MANAGEMENT OF RADIOGRAPHIC CONTRAST MEDIA	***Medication Management (MM)*** **Page 1 of 2**

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

PURPOSE:

To address the safe use of radiographic contrast media throughout Sierra View Medical Center (SVMC).

POLICY:

A. Selection of Contrast Media

Pharmacy & the Pharmacy and Therapeutics Committee must approve contrast media selected for use in the organization. Such media will be made part of the medication formulary (inventory).

B. Procurement of Contrast Media

Contrast media will be procured by Pharmacy, or by a department of the organization utilizing procurement procedures that have been approved by Pharmacy.

C. Delivery of Contrast Media

Contrast media is first delivered to the pharmacy and then it may be delivered directly to the utilizing department so long as the media is delivered to a secure area and to an individual(s) authorized by scope of practice and organization policy to access medication.

D. Storage of Contrast Media

Contrast media will be stored in accordance with manufacturer specifications for light, temperature, and shelf life. Pharmacy must approve all storage areas outside of the main pharmacy. Pharmacy will assure that storage areas are inspected at least monthly.

E. Ordering of Contrast Media

Contrast media may be ordered only by those individuals authorized by license, scope of practice, and organization policy to order medications. Individuals ordering contrast media must be knowledgeable in the recognition and treatment of adverse events involving contrast media.

- For the Radiology Department Only

Prior review of non-emergent intravenous contrast media orders by a pharmacist is not required if the patient is under direct supervision of the physician & the physician controls the ordering, preparation, and administration of the medication or when a delay would harm the patient in an urgent situation. For the purposes of this policy, direct attendance by the physician means that a physician is immediately available to respond to an adverse event involving the use of contrast media.

New orders for oral and rectal contrast media do not require prior review by Pharmacy provided the following conditions are met:

- The oral media is ordered only by those individuals authorized by license, scope of practice, and organization policy to order medications, or in accordance with protocols approved by Pharmacy.
- The oral media is administered only by those individuals authorized by license, scope of practice, and organization policy to do so.
- The oral media is administered in accordance with manufacturer instructions and/or in accordance with protocol(s) approved by Pharmacy.
- Pharmacy conducts a periodic random sampling (quarterly) retrospective audit of oral media use to assure that such use is safe and appropriate

F. Administration of Contrast Media

Contrast media will be administered only by those individuals authorized by license, scope of practice, and organization policy to do so. The media will be administered in accordance with manufacturer instructions and/or in accordance with protocol(s) approved by Pharmacy. Individuals administering contrast media must be aware of the signs and symptoms of adverse effects involving contrast media.

G. Monitoring of Patients Receiving Contrast Media

Patients will be monitored while receiving contrast media by staff sufficiently trained to recognize and respond to a significant reaction or adverse event. The nature and degree of monitoring is not prescribed, but rather is based on the individual clinical needs of each patient, the type of contrast media being used, and the procedure being performed.

H. Reporting of Errors and/or Adverse Reactions

Contrast media is considered a medication. As such, any incidence of an error or adverse reaction will be reported through the Event Reporting software located on the Intranet.

AFFECTED PERSONNEL/AREAS: *PHARMACY DEPARTMENT & RADIOLOGY DEPARTMENT*

REFERENCES:

- The Joint Commission (2023). Hospital accreditation standards. Joint Commission Resources. Oak Brook, IL.
- ACR Manual on Contrast Media (2023). Retrieved on 7-17-23 from https://www.acr.org/-/media/acr/files/clinical-resources/contrast_media.pdf

SUBJECT:	SECTION:
MEDICATION PROCUREMENT, STORAGE, DISTRIBUTION AND CONTROL	*Medication Management (MM)* **Page 1 of 13**

PURPOSE:

To ensure the safe and appropriate use of drug products and drug-related devices at Sierra View Medical Center.

POLICY:

The Pharmacy Department in collaboration and consultation with other professionals, departments and interdisciplinary committees, with approval by the medical staff, is directly responsible for the control and distribution of all stocks of drugs within the organization.

Under this policy, drugs and drug-related devices include, but are not limited to large and small volume injections, orally, topically or intravenous medications, radiopharmaceuticals, diagnostic agents including radiopaque contrast media, anesthetic gases, respiratory therapy drugs, biotechnologically produced drugs,, drugs brought into the hospital by patients or family, and other chemicals and biological substances administered to patients to evoke or enhance pharmacologic responses.

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Control and distribution shall include procurement, recordkeeping, storage and inventory control, compounding, packaging, labeling and disposition.

AFFECTED AREAS/PERSONNEL:

PHARMACY, NURSING, RESPIRATORY THERAPY, DIAGNOSTIC IMAGING, MEDICAL STAFF

PROCEDURE:

I. Procurement

A. The Pharmacist in Charge ~~Director of Pharmacy~~ is responsible for maintaining standards to ensure the quality of all pharmaceuticals used at SVMC. The Pharmacy Department is responsible for the procurement of all pharmaceuticals with the following exceptions:

Large and small volume intravenous solutions without additives.

B. The PIC is responsible for specifications as to the quality, quantity and source of supply of all drugs used in the hospital. Special consideration is given to the current ASHP Guidelines for Drug Distribution and Control, as well as the USP-NF. The Pharmacist in Charge ~~Director of Pharmacy~~ evaluates the acceptability of manufacturers and distributors. Said pharmacist has the authority to reject a particular drug product or supplier if quality is an issue.

C. Procedure:

1. Restocking Pyxis machines will be performed at times scheduled by the Pyxis administrator at the direction of the Pharmacist in Charge. The restock quantities will be based on reports generated by the system to reach pre-set par levels. All individuals that retrieve medications from these systems have a responsibility to ensure accurate dispensation to preserve the integrity of the restocking system. Inaccuracies will be reported to SVMC's error reporting system.

2. Requirements for medications and supplies are determined by a combined list of replacements from pharmacy stock and/or by evaluating minimum and maximum levels on high cost and/or fast moving items on a daily basis. Pharmaceuticals are ordered through the wholesaler's computer interface.

3. When the order is received, the contents of the order are verified against the invoice and/or stickers. All items are stickered and placed into stock. Special handling items i.e., refrigerated.

4. Hazardous drugs will be received and stored in areas designated for HD medications.

5. Controlled substances are checked in and placed in the controlled substances safe in accordance with separate policy (see Controlled Substance Policy).

6. Invoices are matched with purchase orders and original forms and given to the pharmacy buyer for processing. Copies are retained in the pharmacy and originals are coded and forwarded to accounts payable for processing.

7. Items not ordered through the wholesaler, (i.e., IV solutions, blood fraction Products, other specialty items) are matched to the packing receipt and given to the pharmacy buyer for processing.

II. Storage and Control

A. All Pharmaceuticals are stored according to the manufacturer' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions. In addition, all pharmaceuticals are stored under proper environmental conditions (i.e., proper temperature, light, humidity, conditions of sanitation and segregation). Storage areas must be secure, fixtures and equipment used to store drugs will be constructed to limit access only to designated and authorized personnel. Proper consideration is given to the safe storage of poisons and flammable compounds. Internal medications are stored separately from external medications. Non-medications and flammables are not to be stored in medication refrigerators.

1. Room Temperature – Room temperature, as it applies to medication storage shall be between 15°C (59°F) and 30°C (86°F). Medication rooms and drug storage area temperatures will be maintained within this range. Plant Maintenance will notify pharmacy if the temperature in the storage area falls below or is above this specified range. Medications will be relocated to another storage area until the problem is corrected. The pharmacist will be consulted to insure proper relocation.

2. Refrigerator Temperature - Refrigerator temperature, as it applies to medication storage shall be between 2.2°C (36°F) and 7.7°C (46°F). Medication refrigerator temperatures will be maintained within this range. If the temperature is not within the specified range, both the Pharmacy and Plant Maintenance will be notified immediately. Medications will be relocated to another storage area until the problem is corrected. The pharmacist will be consulted to insure the proper relocation of medications. Action(s) taken will be documented either directly on the Refrigerator Temperature Log or in the temperature monitoring software system.

3. Freezer Temperature - Freezer temperature, as it applies to medication storage shall be below -1°F to -50° F) for all pharmaceuticals requiring freezer storage except Cervidil which shall be stored separately in a freezer with the temperature range of -4° F to 14° F. Medication freezer temperatures will be maintained within this range. . If the temperature is not within the specified range, both the Pharmacy and Plant Maintenance will be notified immediately. Medications will be relocated to another storage area until the problem is corrected. The pharmacist will be consulted to insure the proper relocation of medications. Action(s) taken will be documented either directly on the Freezer Temperature Log or in the temperature monitoring software system. "Frozen" antibiotics will be maintained at a temperature not to exceed manufacturer recommendations.

   Note: *Only freezers rated for cryogenic temperatures (below -20°C) are acceptable for medication storage. Freezer compartments of refrigerators are not acceptable for medication storage.*

   Each refrigerator/freezer will have a serviceable thermometer or other temperature-recording device capable of monitoring temperatures within the range required.

   Wireless monitoring system that actively records temperatures every fifteen minutes, twenty-four hours a day, seven days a week will alert engineering to any temperature excursions. Engineering will then in turn contact the pharmacy during normal business hours or the on-call pharmacist if excursions occur after normal business hours.

4. All refrigerators and freezers in the pharmacy are connected to back up emergency power so that in the event of a power failure medication storage temperature will be maintained in an acceptable range.

4. Return to Storage

a. Nursing

i. Medications issued by the pharmacy (not obtained from Pyxis) that are discontinued by the physician or upon discharge will be returned to pharmacy. These medications are to be placed in the designated box labeled "return to pharmacy".

ii. Medications obtained from Pyxis that are unopened and not used can be returned to the "return bin" in Pyxis.

b. Pharmacy

i. Medications returned to pharmacy will be removed from the designated pharmacy return boxes by the pharmacy staff during regularly scheduled rounds.

ii. Unused and unopened medications issued by the pharmacy will be credited to the proper patient's account regardless of the ability to re-issue that medication to another patient.

iii. Medications that are expired or close to expiration will be disposed of according to PHARMACEUTICAL WASTE policy.

iv. Medications removed from Pyxis during monthly floor inspections that are expired or close to expiration will be disposed of according to HAZARDOUS MATERIALS AND WASTE MANAGEMENT PLAN.

III. Control and Security/Accountability

A. Pharmacy – The pharmacy is locked at all times. Only pharmacists will have keys to the pharmacy. During the hours, which the pharmacy is open; pharmacy technical personnel have limited access to the pharmacy during normal pharmacy hours through a pass coded, lock system, while under the supervision of a pharmacist. Non-Pharmacy personnel must have permission from an on duty pharmacist to enter the pharmacy.

B. Controlled Substances – All controlled substances of schedules C-II through C-V will be under a double lock system. A lockable door (i.e., outside door of a medication room or

main pharmacy) qualifies as one lock. Within the main pharmacy, controlled substances of schedules C-II through C-IV will be under a double lock system. Procedures for documentation and recording can be found under ("Pharmacy – Controlled Substances Procedures and/or Nursing – Controlled Substances – Procurement, Administration and Documentation).

C. Medication Rooms – Medication rooms are to remain locked at all times. Only authorized personnel will have access to medication rooms. Authorized personnel will include, but are not limited to Registered Nurses, Licensed Vocational Nurses, and Respiratory Therapists. Other hospital employees who access any medication room must be given authorization and must be observed by nursing or pharmacy staff.

D. Pyxis – Lockable medication cabinets are used to store unit-of-use medications in the patient medication dose system. These medication cabinets will be locked when not attended. Access to medication cabinets will be limited to licensed nursing and pharmacy personnel. The Pyxis cabinets maintain control and storage of medications for various nursing units and keeps specific documentation of all transactions in regards to distribution and dispensing.

E. Large and Small Volume IV Solutions – Certain plain IV solutions are purchased and distributed by the materials management department. These solutions are stored either in the materials management department (considered a limited access area) or in the medication rooms in specific patient care areas. Distribution and control of these solutions are under the guidelines of the pharmacy medication distribution system. These solutions are inspected monthly by pharmacy when completing unit/area inspections.

F. Radiopaque Contrast Media – Radiographic contrast media is purchased by pharmacy, stored and used by the diagnostic imaging department. These medications are controlled with limited access. These medications are inspected monthly by pharmacy when completing unit/area inspections.

G. Radiopharmaceuticals – Radiopharmaceuticals are ordered from a certified/licensed distributor and delivered directly to the "hot lab" in Nuclear Medicine. Policies, procedures and protocols for handling, administration and disposition of radiopharmaceuticals are maintained by the Nuclear Medicine Department of Diagnostic Imaging Services. The Manager ~~Director~~ of Pharmacy confers with the Chief Nuclear Medicine Technologist annually to review these policies, procedures and protocols.

Drug Samples – Drug samples are not allowed at SVMC under any circumstances.

H. Pharmaceutical Sales Representatives – All representatives MUST sign-in with the pharmacy and are ONLY allowed in the pharmacy unless access to other areas in the hospital is approved.

IV. Inspection and Disposition:

A. Inspections – All units and/or areas where medications are used or stored will be inspected by pharmacy staff under the direct supervision of a pharmacist no less frequently than every 30 days. The pharmacy staff during such inspections will ensure that at a minimum:

1. Individual patient medications, except those that have been left at the patient's bedside are returned to pharmacy for appropriate disposition.
2. All drug labels are legible and in compliance with state and federal regulation.
3. Test agents, germicides, disinfectants and other household substances are stored separately from drugs.
4. External use drugs are segregated from drugs for internal use.
5. Drugs are stored at appropriate temperatures.
6. Drugs are accessible only to responsible personnel designated by the hospital.
7. Drugs are not kept in stock after the expiration date on the label and no contaminated or deteriorated drugs shall be available for use.

Findings of unit/area inspections and corrective action(s) required, if any, are discussed with the unit/area supervisor. The unit/area supervisor will acknowledge this by signing the inspection form along with the pharmacist conducting the inspection. A report of findings is provided for the V.P. of Patient Care Services and/or the Chief Nursing Officer. Documentation of inspections is retained for 3 years.

B. Return and Disposal of Medications:

All expired or contaminated medications will be quarantined from Pharmacy stock and sent to a certified pharmaceutical recovery service that is under contract with the facility. The quarantined medications shall be logged into a record (drug return log) that contains at least but not limited to the following information: the date quarantined, name and strength of the medication, its NDC (national drug code) number, quantity, lot number, and the signature of the pharmacy staff that quarantined the medication. The contracted recovery service will conform to FDA and DEA guidelines. The recovery service will meet the following service guidelines:

1. Registered Pharmacist on staff.
2. Be a licensed DEA Registrant.

3. Be DEP/EPA registered large quantity hazardous waste generator.
4. Utilize a licensed hazardous waste transporter.
5. Utilize a licensed hazardous waste processing firm for incineration of disposable products.
6. Maintain general liability insurance.
7. Field Service Technicians are bonded and have Power of Attorney to handle narcotics.
8. Provide documentation or return and/or disposal in accordance with FDA and DEA guidelines.

Copies of the recovery service company's current Controlled Substances Registration Certificate, State Restricted Prescription Drug Distributor License and Department of Environmental Protection DEP/EPA ID Certificate will be maintained in the recovery services binder.

At least quarterly, or more frequently as required the recovery company will be notified to send a Field Service Technician to the Pharmacy to inventory and prepare returned items for shipping.

The recovery service Field Service Technician will segregate controlled substances (C-II through C-V) from non-controlled substances. Schedule II medications will be written up on a DEA Form 222. Schedule III, IV and V medications will be recorded on a Controlled Substances Inventory and Transfer. The original of the DEA Form 222 and the Controlled Substances Inventory and Transfer forms will be retained in the Pharmacy and Copies will be sealed with the separated medications and used as a packing list. Duplicate copies will be sent to the recovery service by the Field Service Technician. All non-controlled substances returned according to the drug return log shall be inventoried, signed, and dated by the recovery service field service technician.

The recovery service Field Service Technician will generate a shipping bill and seal all containers for shipping through a bonded transport service.

Upon receipt of the boxed medications, the recovery service will generate the following documentation:

- Credit Tracking Report – for all items being returned to manufacturers for credit by total Calculated Return Value.

- Manufacturer Return Report – details all items returned by NDC #, description, lot #, expiration date, price and quantity by manufacturer.
- Disposal Report – details all items sent for destruction (incineration) by NDC #, description, lot #, expiration date, price and quantity by manufacturer.
- Disposal Report (Hazardous) – details all hazardous items sent for destruction (incineration) by NDC #, description, lot #, expiration date, price and quantity by manufacturer.
- Controlled Substance Inventory Schedule III – V Destruction Certificate - certifies incineration of schedule III – V medications.
- Copy of the Waste Manifest for Schedule C-II through C-V.
- Schedule Medication Incineration Certificate

The above documentation is maintained in the recovery services binder in the pharmacy and reconciled. Original copy of DEA form 222 is mailed to the DEA.

Waste Management and Accountability (On-site disposal)

Disposal of medication waste within the department shall be controlled and accountability held by the ~~-~~Pharmacist in Charge~~Director of Pharmacy~~. Pharmacy Staff shall dispose of waste in a manner that is consistent and complies with state and federal regulations.

C. Wasting of Medications
(1) Controlled substances will be wasted as per SVMC's CONTROLLED SUBSTANCES policy.

(2) Non controlled medications will be wasted as per SVMC's PHARMACEUTICAL WASTE policy.

V. Distribution of Medications

The pharmacy will dispense all drugs in single unit of use (unit dose) packaging whenever practical and placed in automated dispensing machines.

A. Medications are contained in, and administered from, single unit or unit dose packages.

B. Medications are dispensed in ready-to-administer form to the extent possible.

C. For medications not available in an automated dispensing machine, not more than a 72 hours supply of doses is provided to or available at the patient-care area at any time.

D. A patient medication profile is concurrently maintained in the pharmacy for each patient.

VI. Blood Derivatives

Blood derivative products such as albumin, gamma globulin, immune globulin, etc., are procured and dispensed exclusively by the pharmacy department. Rh_o(D) Immune Globulin is procured by the pharmacy department and distributed to the Laboratory Blood Bank. The blood bank tracks the receipt and dispensing to patients by lot number, using the same procedure as tracking human blood.

VII. Guidelines For Product Dating

All medications at SVMC will be stored in accordance with the most recent guidelines as established by the United States Pharmacopeia (USP) and The National Formulary (NF), and recommendations form the Centers for Disease Control and Prevention (CDC). Consideration is given to the American Society of Health System Pharmacist (ASHP) practice standards.

General Guidelines:

All multi-dose *INJECTABLE* medication containers will be refrigerated after opening, unless specifically labeled "*Do Not Refrigerate*".

Form Specific Guidelines:

1. Injectable:

   a. Ampules – Discard immediately after use. Always use a filter straw.

   b. Single Dose Vials – Discard immediately after use.

   c. Multi-Dose Vials – Discard when empty, when suspected or visible contamination occurs, or if unopened when the manufacturer's expiration date is reached. If opened, use 28 days as expiration or as recommended by manufacturer's guidelines.

   d. Insulin products- 28 days after opening. Must label with expiration date.

2. IV Solutions – Admixed

   a. Mixed on the unit/patient care area – 24 hours after mixing.

b. Mixed in the Pharmacy – As indicated on the IV labels by the pharmacist.

3. IV Solutions – Unmixed

   a. IVPB's and LVP's over 100ml– 30 days after removal of the moisture protective wrapping.

   b. IVPB under 100ml- 15 days after removal of the moisture protective wrapping.

4. Irrigation Solutions

   a. Sterile Saline & Water – 24 hours from opening.

5. EENT Solutions- 1 year after opening or manufacturer's expiration date whichever is first.

   a. Nasal solutions/sprays

   b. Ophthalmic

   c. Otic

6. Nitroglycerin

   a. Sublingual – 6 months after opening.

7. Oral Liquids & Solids

   a. Non-repackaged – manufacturer's expiration date.

   b. Re-packaged – 1 year from date of repackaging or manufacturer's expiration date, whichever is shortest.

8. Topicals- 1 year after opening or manufacturer's expiration date, whichever is first.

   a. Solutions – manufacturer's expiration date if not repackaged or opened.

   b. Ointments, Creams

9. Non-sterile Compounded Medications

a. Orals & Topicals – consult either, Remington's Pharmaceutical Sciences, U.S. Pharmacopeia or medical literature for sterility, stability data. May not be more than 1 year from date of compounding.

VIII. Drug Supply Chain Security Act

As of August of 2023, the FDA has signaled a delay in enforcement action until November 27th, 2024 as they have acknowledged that U.S interoperable systems may need additional time to stabilize and be fully interoperable. SVMC will continue our efforts to work with our third party software to implement the necessary measures and follow the below process to satisfy the enhanced drug distribution security requirements as our partners come online with their systems.

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Trading Partner Verification

A. SVMC will maintain a complete list of drug suppliers and other trading partners. Any company from which SVMC buys pharmaceutical products or to which pharmaceutical products are sold may be a trading partner and their license must be verified prior to business taking place.
B. Prior to doing business with a new supplier or trading partner, SVMC will check the state and/or federal registration licensure status of each by one of the following methods.
    a. Type in the company name in the federal database and look up the address for the facility with which business will be conducted:
    http://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/index.cfm
        i. Each facility will have its own license. Make sure an out of state supplier is authorized and licensed to sell pharmaceuticals in California.
    b. Check California Board of Pharmacy for licensure verification
    c. Ask supplier to provide a copy of their state or federal license or registration. The document should reflect authorization to sell products in California
    d. Document the supplier's licensure expiration data and make a note to review prior to its expiration.
C. SVMC will check the licensure or registration of any new supplier or trading partner prior to purchasing with the supplier.

Transaction Data Capture and Maintenance

1. SVMC will utilize software (Tracelink) for receiving, storing, and retrieving the transaction data of prescription drugs as defined by 503(b) (1) for six years after the transaction.
2. Before accepting delivery of an order, SVMC will review the transaction data to confirm that it matches the physical product received. After acceptance within Tracelink, store the data for future reference as required by DSCSA. This will be held and searchable/retrievable on demand for 6 years.
3. Exempt from the definition of "prescription drugs" are the following:
    a. Intravenous drug that, by its formulation is intended for the replenishment of fluids and electrolytes (such as sodium, chloride and potassium) or calories (such as dextrose or amino acids).
    b. Intravenous drug used to maintain equilibrium of water and minerals in the body, such a dialysis solution.

c. A product intended for irrigation or reconstitution
d. Medical gases
e. Contrast agents or "imaging agents"
f. Medications that may be purchased as OTC (over the counter).

Product Resales

I. At the time of a sale of product to another pharmacy, SVMC will use Tracelink to complete the following actions:
   a) Make a copy of the prior Transaction information & History
   b) Add the new transaction information from the pending sale to the document. New information should include; order date, ship date, product information (name, strength, dosage), NDC, container size, number of containers, lot number, expiration date, your pharmacy name and address and the purchaser's name and address.
   c) Add a transaction statement by including the following language: "Seller has complied with each applicable subsection of FDCA Sec. 581(27)(A)-(G)."
   d) Send the revised transaction data long with the sold product but maintain a copy for SVMC files.
   e) Retain outgoing data for sold products in Tracelink for 6 years.

Suspect Product Investigation

II. A suspect product is one that there is reasonable belief the product may be counterfeit, stolen, unintentionally adulterated, obtained fraudulently, or otherwise unfit and would cause potential harm or death.

III. In the course of normal daily responsibilities, SVMC staff will remain alert for visual clues that a product appears different or is suspect. This includes review of any information which may give SVMC staff a reason to suspect that a supplier may be untrustworthy or fraudulent (e.g state license expired, inconsistent customer service or product delivery, etc.). Supplier behavior or any inquiry by state or federal authorities all may be reason to suspect a product and start an investigation, even if the product does not appear counterfeit.

IV. Suspect product will be managed via the Tracelink application & the following actions should take place.
   a) Inform the PIC about the suspect product.
   b) Place the item in quarantine & clearly mark the product as such. Place product in a temperature appropriate lockable location away from normal inventory.
   c) Conduct an investigation of the suspect product, which should be completed timely as required by DSCSA (within a few days).
   d) Inspect the product carefully & review transaction data. Inquire from trading partner for clarification as needed. Additionally the manufacturer should be reached out to for assistance with determining product legitimacy.
   e) Notify the supplier, the FDA, and the state Board of Pharmacy if evidence of fraud or tampering. To notify the FDA, use Form 3911, which can be located here: http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm. The form should be emailed to FDA at DrugNotifications@fda.hhs.gov.

f) SVMC will keep a product sample and await further instructions from either the FDA, state board of pharmacy, manufacturer or supplier.
g) Records of documentation of the investigation will be maintained for an additional 6 years.

REFERENCES:

- "Best Practices for Health-System Pharmacy, Positions and Practice Standards of ASHP", American Society of Health System Pharmacists, 1999 – 2000, ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control, pp. 74 – 82.
- ~~FDA definition of drug recall classes~~FDA's role in Drug Recalls, from https://www.fda.gov/drugs/drug-recalls/fdas-role-drug-recalls, access on March 21st, 2022. ~~http://www.fda.gov/oc/po/firmrecalls/recall_defin.html - Accessed on May 20th, 2008.~~
- "Guideline for Prevention of Intravascular Device-Related Infections", Public Health Service, U.S., Department of Health and Human Services, Centers for Disease Control and Prevention, Am J Infect Control 1996;24:262-93.
- The Joint Commission (2022~~19~~). Hospital accreditation standards. Joint Commission Resources. Oak Brook, IL.
- The United States Pharmacopeia, 24th Rev., and The National Formulary, 19th Ed. (USP24/NF19) Supplement, 1999; 25:2589-90.
- "Revised USP Standards for Product Dating, Packaging, and Temperature Monitoring", Am J Health-Syst Pharm, Vol 57, Aug 1, 2000:1441-1445.
- State of California, Title 22, § 70263 – 70269
- "Self-Assessment Manual for Proper Management of Medical Waste", The Self-Assessment Project Partnership between the Ca. Dept. of Health Services and the California Healthcare Association. March 16, 1999, Second Ed. Revised, pp 13-14.

CROSS REFERENCES:

- Pharmacy Manual – "Controlled Substances"

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SUBJECT:	SECTION:
NASOGASTRIC/NASOINTESTIONAL TUBE INSERTION AND PLACEMENT VERIFICATION UTILIZING THE KANGAROO FEEDING TUBE WITH IRIS TECHNOLOGY IN THE ADULT PATIENT	***[Enter manual section here]*** **Page 1 of 5**

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

PURPOSE:

To outline Nursing practice for insertion of the Kangaroo Feeding Tube with IRIS technology.
To define placement verification practices for Kangaroo Feeding Tubes placed utilizing the IRIS Technology.

DEFINITIONS:

1. **IRIS** (Integrated Real-time Imaging System) Technology

2. **Advancement:** for the purposes of this clinical guideline, advancement refers to passing SBFT from the stomach through the pylorus into the small bowel. Advancement typically involves prokinetic agents and patient positioning. Gastric insufflation can facilitate advancement and is an advanced nursing skill performed in the ICU requiring additional training

3. **Small Bore Feeding Tube (SBFT):** this refers to a single lumen tube with or without a stylet passed through either the nasal or oral route into either the stomach or small bowel. Oral insertion is restricted to Critical Care.

POLICY:

Use of IRIS technology to insert Nasogastric/Nasolintestinal tube placement may be used by a trained RN in all adult patients contraindications include:

A. Adult patients who have had gastric, esophageal or nasopharyngeal surgery within the past 14 days.
B. Patients with presumed bleeding from esophageal varices.
C. Patients with esophageal obstruction.
D. Active duodenal and/or gastric ulcers;
E. Active bleeding hemangioma;
F. Acute facial, nasal or sinus injuries;
G. Patients with head and neck surgical reconstruction
H. Recently bleeding or banded esophageal and/or gastric varices (within 7 days), ulceration, hemangioma (risk of causing trauma)
I. Patients with basilar skull fracture or facial fractures.
J. Any other patient who in the nurse's judgment would have increased potential for complications from this procedure.

AFFECTED PERSONNEL/AREAS: *All patient care areas*

GUIDELINES:

SUBJECT:	SECTION:
NASOGASTRIC/NASOINTESTIONAL TUBE INSERTION AND PLACEMENT VERIFICATION UTILIZING THE KANGAROO FEEDING TUBE WITH IRIS TECHNOLOGY IN THE ADULT PATIENT	***[Enter manual section here]*** **Page 2 of 5**

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

1. A Prescriber order is required for the initial insertion of a SBFT. This order should clearly indicate the final placement (gastric vs small bowel) as SBFT is sometimes interpreted as "small bowel feeding tube.
2. SBFT can be inserted to the stomach and/or advanced to the small bowel by nursing any time of day if a x ray is ordered pot for verification
3. **ICU Only**: Gastric insufflation shall be discussed with and ordered by the Prescriber prior to commencing the procedure if contraindications are present. Contraindications to gastric insufflation include:
    a. Active gastric ulcer
    b. Esophageal, stomach or duodenal surgery
    c. Active bleeding, esophageal varices within 7 days.
4. A maximum of two attempts to insert a SBFT into the stomach or advance SBFT to the small bowel shall be permitted per inserter. A final third attempt by a different healthcare provider with Prior Experience is permitted. If unsuccessful after third attempt, contact the Prescriber to discuss alternative insertion methods or nutrition options. Rationale for further action shall be documented in the health record by the healthcare provider.
5. Initial gastric or small bowel placement **must** be confirmed by X-ray before a SBFT can be irrigated or used for medications or enteral feeding.
6. Initial gastric or small bowel placement **shall not be** confirmed by auscultation with air bolus, characteristics of aspirates, or pH testing.
7. Ongoing placement confirmation is done by measuring the external length of the SBFT and comparing it to the documented external length at insertion.
    a. When significant discrepancies in external length exist, X-ray confirmation of placement must be repeated.
8. For gastric placement do not remove the stylet, if applicable, until the X-ray is read and final placement is confirmed by a Prescriber or Radiologist. For small bowel placement, remove the stylet prior to attempting spontaneous migration
9. The stylet wire should never be forcefully removed from a SBFT while situated in a patient. If the wire is stuck, notify Prescriber prior to removal of the SBFT.
10. A 20 mL or greater enteral syringe must be used when attempting to aspirate or flush the SBFT. Using a smaller syringe can cause excessive pressure resulting in collapse or rupture of the SBFT. Do not aspirate through a SBFT placed in the small bowel.

PROCEDURE:

Procedure for feeding Tube Placement

1. Power the console on.
    A. Press the power button. The system should start up shortly after and display a login screen.

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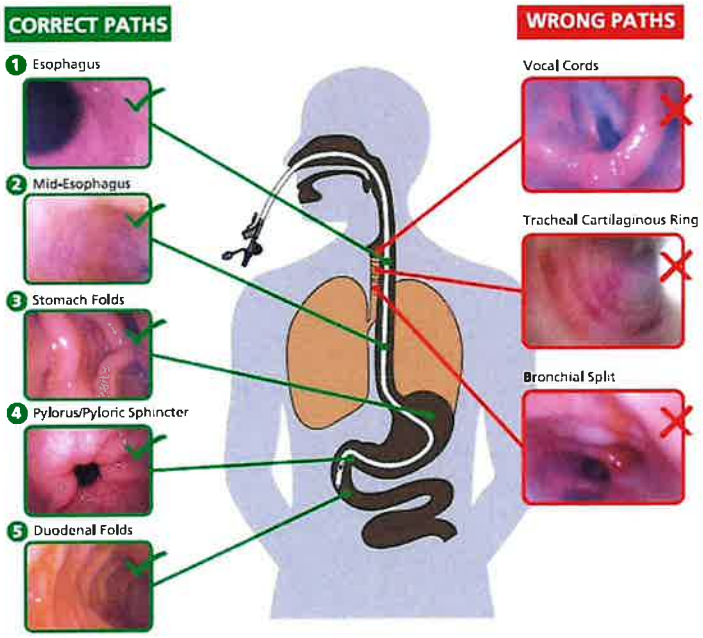
2. Enter login, password, and patient information.
    A. The system will request a login name and password. After typing, tap the check mark to proceed to the main menu.
    B. The main menu will appear. Tap on the procedure icon to begin the placement procedure.
    C. Follow the screen commands to enter the patient information. Patient ID is the patients MRN. All of this information needs to be entered correctly. When complete, tap the check mark to proceed.
    D. The system will ask for confirmation that the information is entered correctly. If yes, tap the check mark. If not, tap the red "x" to go back and re-enter the information.
3. Position patient and estimate feeding tube length.
    A. Position patient for feeding tube placement.
    B. To estimate insertion depth, use the tube to measure the distance from the tip of the patient's nose to the earlobe and from the earlobe to the xiphoid process for gastric placement. Add approximately 10 (ten) inches (25 cm) for intestinal placement. Spontaneous transpyloric passage of the tip often occurs within 24 to 48 hours.
        - Note: The Kangaroo feeding tube with IRIS technology tip is marked with an arrow on the tube near the feeding eyelets. The tip housing camera has optimal flexibility to bend in two directions, either towards or away from this arrow.
4. Activate Hydromer coating.
    A. Use water to activate the Hydromer coating on the Kangaroo feeding tube with IRIS technology, submerge tip for about 5 seconds to activate the Hydromer coating.
        - Note: If applying lubricant, do not put lubricant on or near the camera-side of the feeding tube. The camera vision may become blocked or blurred.
5. Connect interface cable to console.
    A. After entering patient information, the console will request a feeding tube to be attached.
    B. Connect the larger end of the interface cable to the console.
6. Connect interface cable to feeding tube.
    A. Connect the smaller end of the interface cable to the feeding tube. Once the feeding tube and interface cable are connected to the console, a live feed from the camera will display on the screen.
7. Choose the most patent nare.
    A. Choose the most patent nare and insert the feeding tube with the stylet. Direct the feeding tube posteriorly, aiming the tip parallel to the nasal septum and superior surface of the hard palate. Advance the tube to the nasopharynx, allowing the tip to seek its own passage. Once in place, do not manipulate or pull the stylet back and forth within the feeding tube. When the tube has reached the oropharynx, encourage the patient to swallow.
8. Using console for placement.
    A. While inserting the Kangaroo feeding tube with IRIS technology, utilize the console screen to correctly identify anatomical markers during placement (see path images at below).



9. Ending procedure on the console.
    A. When the procedure is complete and the feeding tube has been placed properly, tap the green check mark.
10. Disconnect the feeding tube from the interface cable.
11. Clean and store the IRIS console according to unit practice.
12. Follow LIP orders for XRAY, if applicable, have physician confirm placement of the feeding tube via radiographic image (x-ray).
13. Once placement has been confirmed, remove the stylet, and begin using the feeding tube.

Reconnecting the console and interface cable to the Kangaroo Feeding Tube with IRIS Technology that is currently placed in a patient.

- A console used to place a feeding tube will retain the memory of which patient is associated to that tube. By re-connecting to the same feeding tube, the console will recognize it and ask for confirmation that the patient data is correct.
- Only the console used during the placement procedure will recognize the feeding tube and associated patient information. If a different console is connected to a pre-placed tube, entering the patient's information is required.

1. Power on and reconnect
    A. Power console on and enter login name and password.
    B. Connect console to interface cable.
    C. Connect interface cable to pre-placed Kangaroo feeding tube with IRIS technology.

2. Confirm patient information:
    A. A screen will pop up with the recognized patient information. Tap the check mark to confirm the information is correct.
    B. If the information is incorrect, tap the "x" to go back to the main menu screen.
3. Focus on procedure screen:
    A. The console will display the procedure screen with a live-feed from the camera on the end of the enteral feeding tube.
4. Adjust the feeding tube as needed and complete appropriate pictures.

PRECAUTIONS, CONSIDERATIONS, AND OBSERVATIONS:

1. Refer to policy N-06.010 Nasogastric/Nasointestinal Tube, Insertion, Placement Verification and Use of in the Adult Patient for other considerations.

RELATED POLICIES:

NP-08.091 Protocol for Lidocaine (Atomized) for Nasogastric Tube Placement

N-06.010 Nasogastric/Nasointestinal Tube, Insertion, Placement Verification and Use of in the Adult Patient

REFERENCES:

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SUBJECT: NON-STERILE COMPOUNDING	SECTION: Page 1 of 9

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

PURPOSE:

In compliance with state and federal laws, this policy defines the process to follow any time two or more ingredients are combined to produce a medication intended for patient use, except for admixing and reconstitution of medications and preparations that are products of sterile compounding.

DEFINITIONS:

1. **Approved labeling-** FDA approved labeling that contains approved information for the diluent, the resultant strength, the container closure system, and storage time. By itself, this is not considered compounding.

2. **Beyond Use Date**- the date, or date and time, after which administration of a compounded non-sterile preparation (CNSP) shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored.

3. **Compounding (Non-Sterile)**- the act of combining or altering ingredients by a pharmacist, or by a pharmacy technician under the direct supervision of a pharmacist, in response to a licensed practitioner's prescription, which produces a medication tailored to an individual patient's special medical needs. This definition does not include mixing or reconstituting commercial products in accordance with the manufacturer's instructions or the product's approved labeling, as these tasks are not considered compounding.

4. **Designated person –** an individual assigned by the PIC to be accountable for the performance and operation of the facility and personnel as related to non-sterile compounding

5. **Integrity**- retention of potency until the expiration date noted on the label.

6. **Potency**- active ingredient strength within +/- 10% of the labeled amount.

7. **Reconstitution**- the return, usually by adding liquid, of a drug previously altered for preservation and storage to its original state for administration to a patient.

8. **Quality**- absence of harmful contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.

9. **Strength**- amount of active ingredient per unit of a CNSP.

POLICY:

Sierra View Medical Center's Department of Pharmacy will follow USP 795 guidelines for non-sterile compounding outlined in this policy to produce safe and effective medications.

AFFECTED PERSONNEL/AREAS: *PHARMACY*

EQUIPMENT:

- Graduated cylinders, mortar and pestle, electronic scale, weighing paper, spatula, glass stir rod.

PROCEDURE:

A. A compounded non-sterile preparation (CNSP) shall not be compounded until the pharmacy has first prepared a written master formula. When the pharmacy does not routinely compound a particular drug preparation, the master formula may be written on the prescription itself.
   a. No CNSP shall be prepared that is essentially a copy of one or more commercially available drug products, unless:
      i. The drug product is a shortage item (ASHP or FDA Database), or
      ii. There is a specific, documented medical need made known to the pharmacist. A copy of the documentation of the shortage or the specific medical need shall be maintained for three years from the date of receipt.
   b. NO CNSP shall be prepared with any component not intended for use in a CNSP for the intended patient population.
      i. Example: Doxycycline for pediatrics

B. Repackaging shall not be considered compounding but must be compliant with USP General Chapter 1178 titled Good Repackaging Practices.

C. Each master formulation record must contain at a minimum:

   1. Active ingredient to be used.
   2. Equipment to be used
   3. The maximum allowable beyond use date.
      i. Referenced source material used to support the assigned BUD; such material shall be readily retrievable at the time compounding and shall be maintained for three years from the date each CNSP is dispensed.
   4. Inactive ingredients to be used.
   5. Process and/or procedure used to prepare the drug.
   6. Quality reviews required at each step in the preparation of the drug.
   7. Containment enclosure system
   8. Post-compounding process or procedures if required.
   9. Instructions for storage and handling of the CNSP

D. Assign each product or batch a unique compounding lot number or reference.

E. For non-sterile compounded drug preparation (s), the beyond use date shall not exceed any of the following (refer to Table 3 and 4 in USP Chapter 795):

   1. The shortest expiration date or beyond use date of any ingredient in the preparation
   2. The chemical stability of any one ingredient in the preparation
   3. The chemical stability of the combination of all the ingredients in the preparation
   4. For aqueous ($a_w \geq 0.60$) formulations, 14 days (refrigerated)

i. Cream or gel
ii. Lotion
iii. Oral solutions and suspensions

5. For non-aqueous ($a_w < 0.60$) formulations
   i. Oral = 90 days (controlled room temperature or refrigerated)
   ii. Non-oral = 180 days (controlled room temperature or refrigerated)

6. A pharmacist, using his or her professional judgment, may establish an extended date if the pharmacist researches literature and applies drug-specific and general stability documentation from the literature; Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.
7. Shorter dating may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
8. BUDs assigned with only a date shall expire at 11:59 pm on that date.

F. Record Keeping

A compounding record for each CNSP will be maintained and includes the following:

1. The master formula-document.
2. Name and strength of the compounded drug product.
3. The date and time the drug product was compounded
4. The identity of the pharmacy personnel who compounded the drug product
5. The identity of the pharmacist reviewing the final drug product
6. The quantity of each component used in compounding the drug product
7. The manufacturer or supplier, expiration date, and lot number of each component
8. The pharmacy assigned reference or lot number for the compounded drug product
9. The quantity of drug product compounded and volume or weight of each unit
10. The BUD of the final compounded drug product

The pharmacy shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding. This can be organized as an "audit trail" that includes a detailed, chronological record of all revisions and updates made by the facility's personnel.

G. The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for 3 years.

H. Before compounding a CNSP, the supervising pharmacist shall evaluate compounding personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection or other medical conditions that could contaminate the CNSP or the environment.

I. All non-sterile compounding will be:

1. Performed in a designated area.
2. Executed with gloves for all activities. They must be replaced in the event of compounding a different CNSP or noticing a soiled or compromised appearance.
3. Prepared accurately and carefully using clean equipment in good working order, and certified if applicable.
4. When a diluent is needed, purified water or sterile water for injection will be used. Tap water is not allowed.
5. If a closed-system processing device is used, a gown and face-mask shall be used.
6. Non-disposable garb shall be cleaned with a germicidal detergent and sanitized with 70% isopropyl alcohol before re-use.
7. Any garbing accommodations shall be documented and the record shall include the name of the individual that granted the accommodation, the date, and description of reasons.
8. Before compounding begins, the pharmacist will check that starting components are correct and accurate.
9. The final product will be accurately labeled with the pharmacy name, the generic name(s) of the principle active ingredient(s) and strength, volume and weight of each ingredient, the route of intended administration, date, expiration date, lot number and initials of person preparing and checking the product. Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance will be labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date.
10. The container or receipt contains a statement that the drug has been compounded by the pharmacy.
11. Appropriate auxiliary labels will be affixed.
12. In addition to checking the final product, the pharmacist will perform quality checks throughout the compounding procedure to verify accuracy.

J. Procurement

1. Preferably, active pharmaceutical ingredients (API) that meet the USP-NF standards of strength, quality, purity and integrity and comply with FDA Good Manufacturing Practices will be used.
2. For all ingredients used a MSDS sheet will be readily available.

K. All equipment utilized to compound drug products are to be calibrated every 12 months prior to use and will be stored, used, maintained and cleaned/disinfected in accordance to manufacturer recommendations. Equipment should be cleaned/disinfected prior to compounding of any product.

1. Staff, utilizing such equipment, will receive training to verify competency.
2. Date and time of each calibration is recorded, maintained and retained in the pharmacy records.