DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	11/19/2024-11/25/2024* FEI NUMBER 1170329

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kimberly D. Russo, Chief Executive Officer

FIRM NAME	STREET ADDRESS
District Hospital Partners LP	George Washington University Hospital, 900 23rd St NW
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Washington, DC 20037-2342	Hospital Blood Bank/Transfusion Services

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Records including signature by the physician requesting the procedure are not maintained of all emergency transfusions including complete documentation justifying the emergency action.

Specifically,

The following records did not include the requesting physician's signature or a complete written justification for the emergency release of units for transfusion in accordance with SOP 131, "Emergency Release of Blood," Effective date: 09.17.18, Version 06:

1. "GWUH Emergency Release of Blood Components Orders" form, identified by Medical Record Number [(b)(4)], did not include the physician's signature. [(b)(4)] plasma units and [(b)(4)] red blood cell (RBC) units were released for transfusion.

2. "GWUH Emergency Release of Blood Components Orders" form, identified by Medical Record Number [(b)(4)], did not include the physician's signature. [(b)(4)] red blood cell (RBC) unit was released for transfusion.

3. "GWUH Emergency Release of Blood Components Orders" form, identified by Medical Record Number [(b)(4)], did not include a written justification. [(b)(4)] red blood cell (RBC) units were released for transfusion.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	La-Tasha M Gunter, Investigator Chanel E Crawford, Investigator	X La-Tasha M Gunter Investigator Signed By: La'tasha Gunter -S Date Signed: 11-25-2024 10:13:35	11/25/2024

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4. "GWUH Emergency Release of Blood Components Orders" form, identified by Medical Record Number [(b)(4)], did not include the physician's signature. [redacted] red blood cell (RBC) unit was released for transfusion.

5. "GWUH Emergency Release of Blood Components Orders" form, identified by Medical Record Number [(b)(4)], did not include a written justification. [redacted] red blood cell (RBC) unit was released for transfusion.

6. "GWUH Emergency Release of Blood Components Orders" form, identified by Medical Record Number [(b)(4)], did not include a written justification. [redacted] red blood cell (RBC) unit was released for transfusion.

7. "GWUH Emergency Release of Blood Components Orders" form, identified by Medical Record Number [(b)(4)], did not include a written justification. [redacted] red blood cell (RBC) units were released for transfusion.

OBSERVATION 2

Records are not concurrently maintained with the performance of each significant step in the processing of each unit of blood and blood components so that all steps can be clearly traced.

Specifically,

In September 2024, April 2024, and August 2023, the blood bank technologists failed to document the comparison of the [(b)(6)] sticker lot number identified at the top of the [(b)(4)] log against the lot number of the [(b)(4)] sticker used for the [(b)(4)] of blood products. Under the same column of the [(b)(4)] log, they also failed to document that the word "NOT" was obscured on the [(b)(4)] sticker, leaving the word "[(b)(4)]" on the label to indicate that the units were [(b)(4)]. These steps were required by SOP #312, "X-Ray Blood [(b)(4)]," Effective Date: July/21/2020,

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Version 01.

Examples include the following:

1. On 9/10/24, the tech identified by initials "[redacted]" failed to document the aforementioned information on the [redacted] log, for unit #W185324077654.

2. On 4/11/24 and 4/8/24, the tech identified by initials "[redacted]" failed to document the aforementioned information on the [redacted] log, for units #W185324020337, #W182124022954, #W185324017450, #W182124060281, #W185324030169, and #W185324030788. Additionally, the same tech who failed to document this information, also performed the quality assurance (QA) review of the [redacted] log for these units.

3. On 4/11/24, the tech identified by initials "[redacted]" failed to document the aforementioned information on the [redacted] log, for units #W185324023121 and #W183324027107.

4. On 4/8/24, the tech identified by initials "[redacted]" failed to document the aforementioned information on the [redacted] log, for units #W185324013851 and #W185324020829.

5. On 8/7/23, the tech identified by initials "[redacted]" failed to document the aforementioned information on the [redacted] log, for unit #W205323193154.

***DATES OF INSPECTION**
11/19/2024(Tue), 11/20/2024(Wed), 11/25/2024(Mon)

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X Chanel E Crawford
Investigator
Signed By: Chanel E. Crawford -S
Date Signed: 11-25-2024 10:14:25

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EMPLOYEE(S) SIGNATURE

La-Tasha M Gunter, Investigator
Chanel E Crawford, Investigator

X La-Tasha M Gunter
Investigator
Signed By: La'tasha Gunter -S
Date Signed: 11-25-2024
10:13:55

DATE ISSUED
11/25/2024

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."