THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

Office of the President
Office 713-792-6000
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Houston, Texas 77030

June 21, 2019

ORIGINAL PLAN OF CORRECTION BY EMAIL & OVERNIGHT DELIVERY

Jeannette Ray, RN
Program Manager
Texas Health and Human Services Commission
Healthcare Quality Section
2521 West Front Street
Tyler, Texas, 75702
Jeannette.Ray@hhsc.state.tx.us

Re: **The University of Texas MD Anderson Cancer Center**
CCN: 450076
Complaint Intake #TX00311802

Dear Ms. Ray:

I am the President of The University of Texas MD Anderson Cancer Center in Houston, Texas ("MD Anderson"). As you know, the Texas Health and Human Services Commission ("HHSC") conducted a substantial allegation survey of MD Anderson from May 13 – May 17, 2019. As a result of alleged deficiencies applicable to Medicare Conditions of Participation ("COPs") discovered during that survey, the Centers for Medicare & Medicaid Services ("CMS") provided a 2567 Statement of Deficiencies (the "2567") alleging certain deficiencies and indicating it removed MD Anderson's deemed status on June 3, 2019.

Based on documentation contained in the enclosed voluntary Plan of Correction ("POC"), MD Anderson believes that it complies with Medicare COPs. Accordingly, MD Anderson requests that you accept the POC as its credible allegation of compliance and that you reinstate its deemed status. MD Anderson assumes that a resurvey will be conducted prior to reinstatement of its deemed status.

MD Anderson Corrective Action

MD Anderson has taken swift and decisive actions in order to ensure compliance with Medicare COPs and to address the 2567. Immediately after the survey, and prior to receiving the 2567, MD Anderson took action to begin addressing those concerns expressed by the surveyors in the exit conference. MD Anderson now has a plan to complete those actions. Those efforts include review of and revisions to relevant policies, review of documentation processes in all areas of the hospital that may be involved in blood component transfusions, internal review of the patient charts discussed with the surveyors, implementation of an audit process, and educational sessions for physicians and staff involved in blood component transfusions and the engagement of experienced consultants. To ensure ongoing Medicare COP

compliance, MD Anderson revised applicable hospital policies, including enhancing the Quality Assurance and Performance Improvement (QAPI) Program to accurately reflect Medicare COP requirements. As you can see, there are specific dates for each action summarized on the POC, and the latest date for those corrective actions that MD Anderson will fully implement to address the deficiencies is **July 10, 2019.** As noted in the POC, MD Anderson will have an acceptable process to complete the training for all 4,300 practitioners on the new informed consent policy, which will be initiated by July 10, 2019. The training for all 4,300 practitioners will be completed by July 16, 2019.

Without conceding that the events for which MD Anderson was cited occurred or were violations of Medicare COPs, MD Anderson hereby submits the attached POC as a credible allegation of compliance of the alleged deficiencies. To the extent that MD Anderson may have deviated from Medicare COPs in the past, the corrective actions detailed in the POC ensure that no such deviation will occur in the future. MD Anderson believes that your review of the POC will lead you to reinstate its deemed status. MD Anderson's expeditious and comprehensive response to the 2567 demonstrates its compliance with Medicare COPs as well as how seriously it took the allegations and its commitment to quality and safety.

Following receipt of the 2567, we conducted further review of certain alleged deficiencies. MD Anderson respectfully submits that Patient #34 did have an executed informed consent for administration of blood components in accordance with MD Anderson's then-current informed consent policy. Nothing regarding this fact is changing MD Anderson's POC as attached.

MD Anderson's Services to the Community

Created by the Texas Legislature in 1941 as part of The University of Texas System, MD Anderson is one of the nation's original three comprehensive cancer centers designated by the National Cancer Act of 1971. Today, MD Anderson is one of the world's largest and most respected centers devoted exclusively to cancer patient care, research, education and prevention. U.S. News & World Report's "Best Hospitals" survey has ranked MD Anderson the nation's top hospital for cancer care for 2018 – 2019. Since the survey began in 1990, MD Anderson has been named one of the top two cancer hospitals, and it has been ranked first 14 times in the last 17 years. MD Anderson's recognition is consistent with its vision of being the premier cancer center in the world, based on the excellence of its people, its research-driven patient care and its science.

MD Anderson's mission is to eliminate cancer in Texas, the nation and the world through exceptional programs that integrate patient care, research and prevention. Its mission also includes education for undergraduate and graduate students, trainees, professionals, employees and the public. In fulfilling its mission, MD Anderson is committed to three essential core values, namely (1) Caring - by its words and actions, to create a caring environment for everyone, (2) Integrity – by working together to merit the trust of its colleagues and those it serves, and (3) Discovery – by embracing creativity and seeking new knowledge.

In FY2018, MD Anderson had 21,118 admissions, 1,458,076 outpatient clinic visits, treatments and procedures, and treated more than 141,600 patients -- 45,000 of whom were new patients. MD Anderson also invested almost $863 million in research and Jim Allison, Ph.D., MD Anderson's chair of Immunology and executive director of the Moon Shots Program's immunotherapy platform, was awarded the 2018 Nobel Prize in Physiology or Medicine in recognition of his invention of immune checkpoint blockade as a treatment for cancer. MD Anderson's cancer clinical trial program is one of the largest of its kind. In FY2018, there were 10,155 patients enrolled in 1,250-plus clinical trials exploring innovative cancer treatments. Truly, MD Anderson is an outstanding institution that is committed to "Making Cancer History"®.

MD Anderson and its Medical Staff members and personnel provide numerous resources to the community including free programs to help people learn how to reduce their cancer risk. MD Anderson is also a significant employer within the community and employs over 20,000 people. MD Anderson is also committed to providing care to all patients regardless of economic status. As part of the MD Anderson Oncology Program at Lyndon B. Johnson Hospital, a team of MD Anderson doctors provides cancer care to underserved Texans in collaboration with Harris Health System. In FY2018, MD Anderson provided more than $170.4 million in uncompensated cancer care.

As this information demonstrates, the local, national and international community relies heavily on MD Anderson to provide crucial cancer research and treatment to individuals who may otherwise go without care as well as a number of valuable services to the community as a whole. Continued removal of MD Anderson's deemed status would jeopardize its Medicare and Medicaid participation, putting at risk hundreds of thousands of people without another source of the unique and high-quality health care services currently furnished by and at MD Anderson.

Conclusion

MD Anderson is a valuable and unique asset to the community it serves. MD Anderson provides much needed and readily available patient care services. MD Anderson believes that it is in compliance with Medicare COPs and has taken prompt and comprehensive actions to ensure that it remains in compliance with Medicare COPs. Based on the actions described above, along with the detailed responses described in the POC, MD Anderson respectfully requests that CMS complete a resurvey and reinstatement of its deemed status.

If you have any questions or require additional supporting documentation with regard to MD Anderson compliance with Medicare COPs or any other related matter, please do not hesitate to contact me at (713) 792-6000.

Very truly yours,

Peter WT Pisters, M.D., MHCM
President
The University of Texas
MD Anderson Cancer Center

cc: Dodjie Guioa (with enclosures)
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Centers for Medicare and Medicaid Services
Conditions of Participation (CoP)
Provider Plan of Correction

Provider Name	The University of Texas MD Anderson Cancer Center	**Provider Identification #**	450076	**Survey Exit Date**	05/17/19
Address	1515 Holcombe Blvd Houston, TX 77030	**Survey Type**	Complaint	**Tags**	All

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
Tag A 000	Through a collaborative effort of The University of Texas MD Anderson Cancer Center's (Hospital) senior leadership, administration, nursing staff, medical staff and the Governing Body, the Hospital has taken prompt and significant corrective actions to ensure compliance with the Centers for Medicare and Medicaid Services (CMS) Conditions of Participation (CoPs) under Tags A043, A115, A131, A143, A144, A263, A385, A392, A397, A409, and A576. Hospital has corrected all alleged deficiencies, has implemented training and monitoring and taken steps for sustained compliance with the CoPs over time to ensure safe, quality care for patients. Accordingly, Hospital respectfully requests that CMS accept this PoC as a credible allegation of compliance and evidence of current and long-term sustained compliance with the CoPs and to reinstate Hospital's deemed status. The Plans of Correction for Tags A043, A115, A131, A143, A144, A263, A385, A392, A397, A409, and A576 are incorporated by this reference.			President Completion Date: July 10, 2019
Tag A 043 Governing Body	Tag A 043. Hospital maintains an effective Governing Body that is legally responsible for the conduct of the Hospital. Alternatively, if Hospital does not have an organized Governing Body, the persons legally responsible for the conduct of the Hospital carry out the functions specified in this part that pertain to the Governing Body.			
A 043(A)	A. In accordance with Texas State law, the President appointed by the Board of Regents serves as the Governing Body of the Hospital, and is legally responsible for the conduct of the Hospital and carries out the functions of the Governing Body specified the CoPs. A Governing Body Charter (which serves as the Governing Body's "Bylaws") was developed by the Governing Body and the	A. The Governing Body Charter was adopted by the Governing Body to confirm the Governing Body's duties and responsibilities under the CoPs, including specifically 42 C.F.R. 482.12, on June 18, 2019. The Chief Operating Officer will ensure education for the ELT, the Chair of the ECMS Committee, and members of the President's Advisory regarding their reporting obligations to the Governing Body.	A. The President will monitor compliance with reporting requirements of the ELT, (including QAPI reporting), the ECMS Committee, Chair of the ECMS Committee, and other Hospital leaders and committees to the Governing Body for 6 months to ensure compliance with reporting obligations. The Governing Body will address any deficiencies in reporting with the Hospital	President Completion Date: July 10, 2019

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	Executive Leadership Team (ELT), and approved by the Governing Body on June 18, 2019. The Governing Body Charter: Reflects the designation of the President as the Governing Body in accordance with Texas State law; Incorporates the responsibilities of the President under Texas State law; Incorporates the responsibilities of the President as the Governing Body under the CoPs, including without limitation the role of the Governing Body for the Medical Staff and Quality Assessment and Performance Improvement (QAPI) Program (See Plan of Correction for Tag A 263, QAPI)); and Requires maintenance of minutes. The Medical Staff Bylaws were revised to clarify the role of the President as Governing Body in accordance with 42 C.F.R. 482.12 and 482.22. The Medical Staff Bylaws were reviewed and recommended for approval by the ECMS on or before June 20, 2019. The Medical Staff Bylaws will be approved by the Medical Staff on or before July 8, 2019. The Medical Staff Bylaws will be approved by the Governing Body on or before July 10, 2019.		leader, Medical Staff leader or committee chair, as applicable. The Governing Body Charter will be reviewed by the Governing Body and ELT annually and revised if necessary to reflect any changes to the CoPs, applicable legal and accrediting standards, any changes to the Hospital leaders with direct reporting to the Governing Body and any changes to the committees reporting to the Governing Body.	

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A 043(B)	B. The Governing Body has been actively involved in the oversight and implementation of the Plans of Correction to ensure that blood component transfusions are administered in accordance with the Hospital's policies and procedures and acceptable nursing standards. The Plans of Correction for Tags A 115, 144, 385, 409 are incorporated by this reference.			Responsible Person: President Completion Date: July 10, 2019
A 043(C)	C. The Governing Body has been actively involved in the oversight and implementation of the Plans of Correction to ensure that nurses continually assess patients during transfusions of blood components, and that vital signs are monitored and any vital signs flagged as abnormal are assessed or reassessed in accordance with Hospital policy. The Plans of Correction for Tags A 115, 385, 409 are incorporate by this reference.			Responsible Person: President Completion Date: July 10, 2019
A 043(D)	D. The Governing Body has been actively involved in the oversight and implementation of this Plan of Correction to ensure nurses notified the physician of changes in vital signs and changes in the condition of patients receiving transfusions of blood components. The Plans of Correction for Tags A 115, 144, 409 are incorporated by this reference.			Responsible Person: President Completion Date: July 10, 2019

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A 043(E)	E. The Governing Body has been actively involved in the oversight and implementation of the Plans of Correction to ensure Hand-Off Communication is performed in transferring patients with infectious disease within the facility, and that isolation precautions for safe care are implemented. The Plans of Correction for Tags A 115, 144 are incorporated by this reference.			Responsible Person: President Completion Date: July 10, 2019
A 043(F)	F. The Governing Body has been actively involved in the oversight and implementation of the Plans of Correction to ensure patients are allowed to make informed decisions regarding their care. The Plans of Correction for Tags A 115, 131 are incorporated by this reference.			Responsible Person: President Completion Date: July 10, 2019
A 043(G)	G. The Governing Body has been actively involved in the oversight and implementation of the Plan of Correction to ensure the protection of patient's personal privacy and dignity. The Plans of Correction for Tags A 115, 143 are incorporated by this reference.			Responsible Person: President Completion Date: July 10, 2019
A 043(H)	H. The Governing Body has been actively involved in the oversight and implementation of the Plans of Correction to ensure the development, implementation and maintenance of an effective, ongoing, hospital-wide, data driven QAPI program. The Governing Body			Responsible Person: President Completion Date: July 10, 2019

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	ensures that the quality program reflects the complexity of the Hospital's organization and services, including services furnished under contract or arrangement, and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The Plans of Correction for Tags A 263 and 576 are incorporated by this reference.			
TAG A 115 Patient Rights	Tag A 115 Hospital protects and promotes each patient's rights. Hospital ensures patient's rights are protected. Specifically, Hospital ensures that: A. blood component transfusions are administered in accordance with Hospital's policies/procedures and acceptable nursing standards; B. nurses continually assess patients during transfusions of blood components, in accordance with Hospital policy; C. nurses notify the physician of changes in vital signs and condition of patients receiving transfusions of blood components, in accordance with Hospital policy; D. Hand-Off Communication are performed in transferring a patient with orders for isolation precautions from one patient location to another patient location, and Contact isolation precautions for safe care are implemented; E. patients are allowed to make informed decisions regarding their care; and F. the patients' personal privacy and dignity are protected by having a X-ray door/room not accessible to the public.			
A 115(A)	A. Hospital ensures that blood component transfusions are administered in accordance with Hospital's policies/procedures and acceptable nursing standards. A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including the CMS/CLIA Steering Committee, members of the Transfusion and Patient Blood Management Committee, the Multidisciplinary Clinical Policies and Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and Transfusion Reaction Policy CLN1115. As part of this review over 6,000 patient charts who received blood transfusions were reviewed.	A. The Associate Director of G9 (Pediatrics) implemented immediate individualized one on one training for the two Pediatric RNs who cared for Patient #34 as follows: Nurse-Day Shift: Trained 12/7/18 and 12/31/18. Training included: • Coached on the escalation of concerns • Coached on appropriate documentation of escalation of concerns/provider notification • Nursing practice when carrying out the plan of care; prioritizing interventions • Reviewed gaps in documentation related to hand-off documentation when the patient leaves the unit Nurse- Night Shift- Trained 12/20/18. Training included: • Gaps in vital sign monitoring and documentation for blood component administration	A. A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by the Office of Performance Improvement (OPI) to determine adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115 for vital signs and monitoring, that orders specify the duration for the transfusion, and the actual duration of the transfusion. OPI reviews the data with the Executive Director of Nursing Quality, Safety and Research, and the Laboratory Medicine Quality and Safety Officer to develop recommendations for improvement. In collaboration with the Executive Director of Nursing Quality, Safety and Research and the Laboratory Medicine	A. Chief Operating Officer Completion Date: July 10, 2019

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	A training program was developed by an inter-disciplinary team, including a transfusion medicine faculty member. This team was led by the Executive Director of Nursing, Professional Practice, Strategy and Execution and the Chief Education and Training Officer to develop curriculum and implement training for Credentialed Providers (Physicians, Advanced Practice Nurses and Physician Assistants) who obtain informed consent for, order, administer or manage complications of blood component transfusions and registered nurses (RN) who administer blood components pursuant to the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes enhanced nursing standards for administering and monitoring blood components. The hospital nurse training "Blood Component Administration Competency" has been updated to include the following transfusion reaction symptoms: dry, flushed skin, pain in the abdomen and extremities, vomiting and bloody diarrhea. The training also addresses signs and symptoms of transfusion associated circulatory overload. Completed May 17, 2019. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was published on May 19, 2019. Under the revised policy, nursing staff are	• Reviewed signs and symptoms of reactions • Coached on appropriate documentation of escalation of concerns/provider notification • Reviewed institutional policy (CLN1115). RNs who administer blood components received educational information delivered in person by unit nursing leadership (Associate Directors, Nurse Managers, or Clinical Nurse Leaders) starting May 16, 2019 and completed by May 24, 2019. The topics addressed included adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, as supported by ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, acceptable nursing standards for assessment, recognition, responding, and reporting symptoms of suspected transfusion reactions. RNs who administer blood components completed mandatory computer based training with knowledge assessment starting May 17, 2019 to be completed by July 10, 2019. The topics addressed within the computer based training on the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes increased monitoring of vital sign and patient assessment, recognizing, responding and reporting transfusion reactions. Material was also reviewed regarding delivering patient education for participation in their care while receiving blood components. Additional training will be conducted regarding the changes to the EHR Blood Component Order Sets, the modifications to the Blood Component Administration and Transfusion Reaction Policy CLN1115 (including the use of volumetric pumps, orders to include the duration of the transfusion, and definitions of hypotension and fever, ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction), and	Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and Patient Blood Management Committee, the ECMS, and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Hospital will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate. Any Credentialed Provider deficiencies will be addressed through pertinent education and training, re-education and/or referral for confidential peer review through the medical staff.	

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	to take the patient's vital signs prior to initiating the transfusion, 15 minutes into the transfusion, hourly from the start of the transfusion through completion of the transfusion, and at completion of the transfusion. They are required to assess the patient for signs and symptoms of transfusion reaction and document their observations hourly through completion of the transfusion, and at completion of the transfusion. The Electronic Health Record (EHR) includes a list of the symptoms of a transfusion reaction. If the nurse selects yes, the EHR generates a checklist of the symptoms allowing the nurse to select the symptoms that are present. To ensure RNs administer blood components in accordance with Hospital policy and acceptable nursing standards: (1) The Blood Component Administration and Transfusion Reaction Policy CLN1115 was further modified to require that blood components are administered via volumetric pump to ensure the duration of the transfusion is in accordance with the physician's orders. (Accordingly, blood components will not be administered via "gravity" flow). The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was approved on June 20, 2019. (2) Based on the National Patient Safety	the Stop the Line for Patient Safety Policy CLN1185, by July 10, 2019. RNs on leave who transfuse blood components must complete training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the enhanced nursing standards for administering and monitoring blood component transfusions, and the Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new RNs who transfuse blood components. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions will complete the computer based training as outlined above by July 10, 2019. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood components and are on leave must complete the computer based training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new Credentialed Providers. A reminder communication will be sent to all nursing staff who administer and monitor transfusions regarding the process for reporting a suspected transfusion reaction, by July 10, 2019.		

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	Network Biovigilance Component Hemovigilance Module Surveillance Protocol, published April 2018 by the Centers for Disease Control the Blood Component Administration and Transfusion Reaction Policy CLN1115 will be amended to include the definitions of hypotension and fever, by July 10, 2019. ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, which supports CLN1115, will be revised to address the hypotension and fever parameters by July 10, 2019. (3) EHR Physician Blood Component Order Set was modified to require duration of blood component transfusion. A Credentialed Provider must specify the duration of the blood component transfusion in order to complete the blood component order (hard stop). This change will be effective by July 10, 2019. (4) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone to stop the line for an incomplete, conflicting or unclear order or in the event of a suspected transfusion reaction. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS approved the updated Stop the Line for Patient Safety Policy CLN1185, which was approved on June 20, 2019. Further training was developed on the EHR Blood Component Order Sets, and the modifications to the Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for			

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	Patient Safety Policy CLN1185. The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20, 2019. Following a 2-4 week prospective pilot in 3 areas where transfusions are administered (Phase 2), the Hemovigilance Unit will track the vital signs of each patient receiving transfusion services in real time (Phase 3). These vital signs will be reviewed by an RN under the supervision of an Advanced Practice Provider (APP) or physician 24/7 to complement the monitoring being provided at the bedside. The real time monitoring will also weight the vital signs and assign a risk number for each patient that is updated in real time, highlighting patients exhibiting potential signs of a reaction. Signs of a reaction will be referred to a member of the transfusion medicine practice. In addition to the monitoring being done by nursing under this POC, the Hemovigilance Unit will also review potential false negatives on an ongoing basis and report to the Transfusion and Patient Blood Management Committee. We are not formally submitting Phase 2			

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	and 3 as part of our corrective action as these require a significant time investment to operationalize it across the hospital but we wanted CMS to be aware of its development as proof of our commitment to being an industry leader in developing new, innovative approaches to delivering the highest level of care. This plan of correction is also addressed under the Plans of Correction Tags A 043, A 144, A 385, and A 409.			
A 115(B)	B. The Hospital ensures that nurses continually assess patients during transfusion of blood components. A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including the CMS/CLIA Steering Committee, members of the Transfusion and Patient Blood Management Committee, the Multidisciplinary Clinical Policies and Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and Transfusion Reaction Policy CLN1115. As part of this review over 6,000 patient charts who received blood transfusions were reviewed. A training program was developed by an inter-disciplinary team, including a transfusion medicine faculty member. This team was led by the Executive Director of Nursing, Professional Practice, Strategy and Execution and the Chief Education and Training Officer to develop curriculum and implement training for Credentialed Providers who obtain informed consent for, order, administer or manage	B. The Associate Director of G9 (Pediatrics) implemented immediate individualized one on one training for the two Pediatric RNs who cared for Patient #34 as follows: Nurse-Day Shift: Trained 12/7/18 and 12/31/18. Training included: • Coached on the escalation of concerns • Coached on appropriate documentation of escalation of concerns/provider notification • Nursing practice when carrying out the plan of care; prioritizing interventions • Reviewed gaps in documentation related to hand-off documentation when the patient leaves the unit RNs who administer blood components received educational information delivered in person by unit nursing leadership (Associate Directors, Nurse Managers, or Clinical Nurse Leaders) starting May 16, 2019 and completed by May 24, 2019. The topics addressed included adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, as supported by the ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, acceptable nursing standards for continual assessment, recognition, responding, and reporting symptoms of suspected transfusion reactions.	B. A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by the OPI to determine adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115 for the for vital signs and monitoring. OPI reviews the data with the Executive Director of Nursing Quality, Safety and Research, and the Laboratory Medicine Quality and Safety Officer to develop recommendations for improvement. In collaboration with the Executive Director of Nursing Quality, Safety and Research and the Laboratory Medicine Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and Patient Blood Management Committee, the ECMS, and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee	B. Chief Operating Officer Completion Date: July 10, 2019

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	complications of blood component transfusions and registered nurses (RN) who administer blood components pursuant to the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes enhanced nursing standards for administering and monitoring blood components. The hospital nurse training "Blood Component Administration Competency" has been updated to include the following transfusion reaction symptoms: dry, flushed skin, pain in the abdomen and extremities, vomiting and bloody diarrhea. The training also addresses signs and symptoms of transfusion associated circulatory overload. Completed May 17, 2019. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was published on May 19, 2019. Under the revised policy, nursing staff are to take the patient's vital signs prior to initiating the transfusion, 15 minutes into the transfusion, hourly from the start of the transfusion through completion of the transfusion, and at completion of the transfusion. They are required to assess the patient for signs and symptoms of transfusion reaction and document their observations hourly through completion of the transfusion, and at completion of the transfusion.	RNs who administer blood components completed mandatory computer based training with knowledge assessment starting May 17, 2019 to be completed by July 10, 2019. The topics addressed within the computer based training on the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes increased monitoring of vital sign and patient assessment, recognizing, responding and reporting transfusion reactions. Material was also reviewed regarding delivering patient education for participation in their care while receiving blood components. Additional training will be conducted regarding the changes to the Blood Component Administration and Transfusion Reaction Policy CLN1115 (including definitions of hypotension and fever, as described in ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction), and the Stop the Line for Patient Safety Policy CLN1185, by July 10, 2019. RNs on leave who transfuse blood components must complete training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the enhanced nursing standards for administering and monitoring blood component transfusions, and the Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new RNs who transfuse blood components. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions will complete the computer based training as outlined above by July 10, 2019. Credentialed Providers who obtain informed consent	and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Hospital will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate. Any Credentialed Provider deficiencies will be addressed through pertinent education and training, re-education and/or referral for confidential peer review through the medical staff.	

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	The Electronic Health Record (EHR) includes a list of the symptoms of a transfusion reaction. If the nurse selects yes, the EHR generates a checklist of the symptoms allowing the nurse to select the symptoms that are present. To ensure RNs administer blood components in accordance with Hospital policy and acceptable nursing standards: (1) Based on the National Patient Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol, published April 2018 by the Centers for Disease Control the Blood Component Administration and Transfusion Reaction Policy CLN1115 will be amended to include the definitions of hypotension and fever, by July 10, 2019. ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, which supports CLN1115, will be revised to address the hypotension and fever parameters by July 10, 2019. (2) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone to stop the line for an incomplete, conflicting or unclear order or in the event of a suspected transfusion reaction. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS approved the updated Stop the Line for Patient Safety Policy CLN1185, which was approved on June 20, 2019. Further training was developed on the modifications to the Blood Component	for, order, administer or manage complications of blood components and are on leave must complete the computer based training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new Credentialed Providers.		

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	Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185. The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20, 2019. Following a 2-4 week prospective pilot in 3 areas where transfusions are administered (Phase 2), the Hemovigilance Unit will track the vital signs of each patient receiving transfusion services in real time (Phase 3). These vital signs will be reviewed by an RN under the supervision of an APP or physician 24/7 to complement the monitoring being provided at the bedside. The real time monitoring will also weight the vital signs and assign a risk number for each patient that is updated in real time, highlighting patients exhibiting potential signs of a reaction. Signs of a reaction will be referred to a member of the transfusion medicine practice. In addition to the monitoring being done by nursing under this POC, the Hemovigilance Unit will also review potential false negatives on an ongoing basis and report to the Transfusion and Patient Blood Management Committee.			

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	We are not formally submitting Phase 2 and 3 as part of our corrective action as these require a significant time investment to operationalize it across the hospital but we wanted CMS to be aware of its development as proof of our commitment to being an industry leader in developing new, innovative approaches to delivering the highest level of care. This plan of correction is also addressed under the Plans of Correction Tags A 043, A 144, A 385, and A 409.			
A 115(C)	C. Hospital ensures that nurses notify the Credentialed Providers of changes in vital signs and condition of patients receiving transfusions of blood components as required under the Hospital policy. A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including the CMS/CLIA Steering Committee, members of the Transfusion and Patient Blood Management Committee, the Multidisciplinary Clinical Policies and Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and Transfusion Reaction Policy CLN1115. As part of this review over 6,000 patient charts who received blood transfusions were reviewed. A training program was developed by an inter-disciplinary team, including a transfusion medicine faculty member. This team was led by the Executive Director of Nursing, Professional Practice, Strategy and Execution and the Chief Education and	C. The Associate Director of G9 (Pediatrics) implemented immediate individualized one on one training for the two Pediatric RNs who cared for Patient #34 as follows: Nurse-Day Shift: Trained 12/7/18 and 12/31/18. Training included: • Coached on the escalation of concerns • Coached on appropriate documentation of escalation of concerns/provider notification • Nursing practice when carrying out the plan of care; prioritizing interventions Reviewed gaps in documentation related to hand-off documentation when the patient leaves the unit Nurse- Night Shift- Trained 12/20/18. Training included: • Gaps in vital sign monitoring and documentation for blood component administration • Reviewed signs and symptoms of reactions • Coached on appropriate documentation of escalation of concerns/provider notification • Reviewed institutional policy (CLN1115). RNs who administer blood components received	C. A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by the OPI to determine adherence to (1) Blood Component Administration and Transfusion Reaction Policy CLN1115, including reporting to and consulting with the Credentialed Provider and the Transfusion Medicine Physician for suspected transfusion reactions, and (2) Stop the Line for Patient Safety Policy CLN1185, to stop the line in the event of a suspected transfusion reaction or an incomplete, conflicting or unclear order. OPI reviews the data with the Executive Director of Nursing Quality, Safety and Research, and the Laboratory Medicine Quality and Safety Officer to develop recommendations for improvement. In collaboration with the Executive Director of Nursing Quality, Safety and Research and the Laboratory Medicine Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and	C. Chief Operating Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	Training Officer to develop curriculum and implement training for Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions and registered nurses (RN) who administer blood components pursuant to the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes enhanced nursing standards for administering and monitoring blood components. The hospital nurse training "Blood Component Administration Competency" has been updated to include the following transfusion reaction symptoms: dry, flushed skin, pain in the abdomen and extremities, vomiting and bloody diarrhea. The training also addresses signs and symptoms of transfusion associated circulatory overload. Completed May 17, 2019. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was published on May 19, 2019. Under the revised policy, nursing staff are to take the patient's vital signs prior to initiating the transfusion, 15 minutes into the transfusion, hourly from the start of the transfusion through completion of the transfusion, and at completion of the transfusion. They are required to assess the patient for signs and symptoms of transfusion reaction and document their observations hourly through completion of	educational information delivered in person by unit nursing leadership (Associate Directors, Nurse Managers, or Clinical Nurse Leaders) starting May 16, 2019 and completed by May 24, 2019. The topics addressed included adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, as supported by ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, acceptable nursing standards for assessment, recognition, responding, and reporting symptoms of suspected transfusion reactions. RNs who administer blood components completed mandatory computer based training with knowledge assessment starting May 17, 2019 to be completed by July 10, 2019. The topics addressed within the computer based training on the Blood Component Administration and Transfusion Reaction Policy CLN1115, included increased monitoring of vital sign and patient assessment, recognizing, responding and reporting transfusion reactions to and consulting with the Credentialed Provider and the Transfusion Medicine Physician, and clarifying physician orders. Material was also reviewed regarding delivering patient education for participation in their care while receiving blood components. Additional training will be conducted regarding the changes to the Blood Component Administration and Transfusion Reaction Policy CLN1115 (including definitions of hypotension and fever, reporting suspected transfusion reactions to and consulting with the Credentialed Provider and the Transfusion Medicine Physician), and the Stop the Line for Patient Safety Policy CLN1185, by July 10, 2019. RNs on leave who transfuse blood components must complete training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the	Patient Blood Management Committee, the ECMS, and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Hospital will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate. Any Credentialed Provider deficiencies will be addressed through pertinent education and training, re-education and/or referral for confidential peer review through the medical staff.	

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	the transfusion and at completion of the transfusion. The Electronic Health Record (EHR) includes a list of the symptoms of a transfusion reaction. If the nurse selects yes, the EHR generates a checklist of the symptoms allowing the nurse to select the symptoms that are present. To ensure RNs notify the Credentialed Providers of condition of patients receiving transfusions of blood components as required under the Hospital policy: (1) Based on the National Patient Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol, published April 2018 by the Centers for Disease Control the Blood Component Administration and Transfusion Reaction Policy CLN1115 will be amended to include the definitions of hypotension and fever, by July 10, 2019. ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, which supports CLN1115, will be revised to address the hypotension and fever parameters by July 10, 2019. (2) The Blood Component Administration and Transfusion Reaction Policy CLN1115 was further modified to require that the Transfusion Medicine Physician is consulted regarding suspected blood component transfusion reactions. (3) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone to stop the line for an incomplete,	enhanced nursing standards for administering and monitoring blood component transfusions, Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new RNs who transfuse blood components. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions will complete the computer based training as outlined above by July 10, 2019. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood components and are on leave must complete the computer based training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 is included in the on-boarding process for new Credentialed Providers.		

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	conflicting or unclear order or in the event of a suspected transfusion reaction. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS approved the updated Stop the Line for Patient Safety Policy CLN1185, which was approved on June 20, 2019. Further training was developed on the modifications to the Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185. The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20, 2019. The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20,			

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	2019. Following a 2-4 week prospective pilot in 3 areas where transfusions are administered (Phase 2), the Hemovigilance Unit will track the vital signs of each patient receiving transfusion services in real time (Phase 3). These vital signs will be reviewed by an RN under the supervision of an APP or physician 24/7 to complement the monitoring being provided at the bedside. The real time monitoring will also weight the vital signs and assign a risk number for each patient that is updated in real time, highlighting patients exhibiting potential signs of a reaction. Signs of a reaction will be referred to a member of the transfusion medicine practice. In addition to the monitoring being done by nursing under this POC, the Hemovigilance Unit will also review potential false negatives on an ongoing basis and report to the Transfusion and Patient Blood Management Committee. We are not formally submitting Phase 2 and 3 as part of our corrective action as these require a significant time investment to operationalize it across the hospital but we wanted CMS to be aware of its development as proof of our commitment to being an industry leader in developing new, innovative approaches to delivering the highest level of care. This plan of correction is also addressed under the Plans of Correction Tags A 043, A 144, A 385, and A 409.			

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
A 115(D)	D. Hand-Off Communications are performed and documented in transferring a patient with isolation precaution orders from one patient location to another to ensure that isolation precautions for safe care are implemented. Nursing leadership reviewed Hand-Off Communication Policy CLN0513 in relation to transfers within Hospital, by June 19, 2019. The Executive Director of Clinical Informatics approved a modification to the EHR Hand-Off Communication documentation for nursing to include isolation precautions. A new flow sheet row will serve as the transferring RN's attestation that the isolation status was communicated to the receiving health care provider. The Executive Director of Nursing, Professional Practice, Strategy and Execution in collaboration with the Director of Education developed and will implement educational training specifically addressing hand-off communication and documentation related to isolation precautions for patient transfers within Hospital in accordance with Hand-Off Communication Policy CLN 0513 and the new documentation. This plan of correction is also addressed under the Plans of Correction Tags A 043, A 144.	D. RNs who provide hand-off communication for patients transferring within Hospital will receive education and training with nurse leadership (Associate Director, nurse manager, clinical nurse leaders and educators) to be completed by July 10, 2019. The topics addressed during the training will emphasize isolation precaution information, adherence to Hand-Off Communication Policy CLN 0513, and documentation and modification enhancements to EHR to include attestation of isolation precautions. RNs on leave who provide hand-off communication for patients transferring within Hospital must complete the training before attending patients Education regarding isolation precaution information, adherence to Hand-Off Communication Policy CLN 0513, documentation and the EHR that includes attestation of isolation precautions will be included in the on-boarding process for new RNs who provide hand-off communication for patients transferring within Hospital.	D. The Hospital will prepare a report reflecting all isolation inpatients with a permanent or temporary hand-off to assess whether the RN attestation of hand-off and isolation precaution was communicated and documented. The report is reviewed weekly by the Executive Directors of Nursing team and the Chief Nursing Officer, who may recommend and implement any appropriate changes. The report will be submitted to the QAPI Council monthly for the initial quarter. After the first quarter, QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. Monitoring and reporting will continue until 100% compliance is documented for two consecutive months. The QAPI Council will review the information, and may make recommendations for further improvement, and provide at least a summation to the ELT and the Governing Body at least quarterly. The Hospital will address any deficiencies with the individual RN through pertinent training, re-education and/or disciplinary action, as appropriate.	D. Chief Nursing Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
A 115(E)	The Hospital has developed an acceptable process to ensure that patients are allowed to make informed decisions regarding their care, including current signed consent forms for transfusion of blood components. An ESC was convened following the CMS hospital survey. The ESC included the Chief Medical Executive, Chief Medical Officer, Chief Operating Officer, Chief Compliance Officer, and Chief Nursing Officer. The ESC made a determination to update the process for blood component transfusions, to ensure patients who receive blood component transfusions receive information and disclosures needed to make informed decisions. An interdisciplinary team, led by the Chief Medical Officer and including the Chief Nursing Officer, Chief Compliance Officer, Associate Vice President (AVP) for Patient Experience, Medical Practice leaders, Nursing leaders, and Information Technology leaders developed a blood component transfusion informed consent policy. The Informed Consent for Blood Component Transfusion Policy CLN3276 requires that patients and/or their representative receiving transfusions of blood components have current informed consents and receive information and disclosures needed to make informed decisions**,** including risks, benefits and alternatives. Specifically, a patient's Informed Consent for Blood Component Transfusion must be renewed (i) every six months, (ii) when a patient signs a consent to	The Electronic Health Record (EHR) System will be updated to build the workflow for the new informed consent process and will be fully tested by July 10, 2019. The Chief Education Officer and Training Officer in conjunction with the Chief Medical Officer will develop computer-based training, with knowledge assessment on the new Informed Consent for Blood Component Transfusion Policy CLN3276 and the Blood Component Administration and Transfusion Reaction Policy CLN1115 for Credentialed Providers (Physicians, Advanced Practice Nurses and Physician Assistants) who obtain informed consent for, order, administer or manage complications of blood component transfusions, and registered nurses (RNs) who administer blood components. The topics to be addressed in this training will include: adherence to Informed Consent for Blood Component Transfusion Policy CLN3276, which includes ensuring patients receiving transfusions of blood components have current informed consents and receive information and disclosures needed to make informed decision, including risks, benefits and alternatives, and are informed of the right to refuse treatments through the opportunity to revoke their consent. In addition, training will be provided on the time frame and circumstances for expiration of blood component transfusion consent thereby ensuring patients will have repeated consent after reassessment. Training will also address nursing documentation to confirm the presence of a current informed consent prior to each episode of blood component administration, and to confirm that the patient has not revoked the consent in accordance with the Blood Component Administration and Transfusion Reaction Policy CLN1115. The EHR workflow will be incorporated into the training program. The training program will be developed by July 10,	Following completion of training and full implementation of the new Informed Consent for Blood Component Transfusion Policy CLN3276 and the associated EHR workflow, a random sample of 93 blood component transfusion records will be audited and analyzed retrospectively each week by OPI to determine adherence to the Informed Consent for Blood Component Transfusion Policy CLN3276. OPI will review the data with the Chief Medical Officer and the Executive Director of Nursing Quality, Safety and Research to develop recommendations for improvement. In collaboration with the Chief Medical Officer and the Executive Director of Nursing Quality, Safety and Research, OPI will submit the information and recommendations for improvement to the ECMS and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a quarterly summation to the ELT and the Governing Body. The Hospital will address any deficiencies with the individual nursing	Chief Medical Officer Completion Date: July 16, 2019.

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	receive a new chemotherapy agent, (iii) when a new primary cancer diagnosis is assigned to the patient, and (iv) any other time the Attending Physician or Physician Designee determines that there is a significant deviation from the course of treatment originally discussed with a patient, or there is a change in a patient's condition or diagnosis that would reasonably be expected to alter the original Informed Consent for Blood Component Transfusion. The Executive Owner of the Policy (the Chief Medical Executive) and the Executive Committee of the Medical Staff (ECMS) approved the Informed Consent for Blood Component Transfusion Policy CLN3276 on June 20, 2019. A training program will be developed by an inter-disciplinary team, led by the Chief Education and Training Officer and the Chief Medical Officer, to develop curriculum and implement training for Credentialed Providers (Physicians, Advanced Practice Nurses and Physician Assistants) who obtain informed consent for, order, administer or manage complications of blood component transfusions and registered nurses (RNs) who administer blood component transfusions. The training program will be developed by July 10, 2019. The Blood Component Administration and Transfusion Reaction Policy CLN1115 was amended to require nursing documentation to confirm the	2019. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions and RNs who administer blood components will receive mandatory computer-based training developed by the Chief Education Officer and Training Officer in conjunction with the Chief Medical Officer. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood components but are on leave must complete the training before attending patients. Education regarding Informed Consent for Blood Component Transfusion Policy CNL3276 and the Blood Component Administration and Transfusion Reaction Policy CLN1115 will be included in the on-boarding process for new Credentialed Providers who order blood components. RNs who administer blood components and are on leave must complete the computer based training before attending patients. Education regarding compliance with Informed Consent for Blood Component Transfusion Policy CLN3276 and the Blood Component Administration and Transfusion Reaction Policy CLN1115 is included in new employee orientation for all RN staff who administer blood components. Training for the new Informed Consent for Blood Component Transfusion Policy 3276 for Hospital's approximately 4,300 Credentialed Providers and RNs who obtain informed consent for, order, administer or manage complications of blood component transfusions will be initiated by July 10, 2019. Hospital will complete the training by July 16, 2019.	staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate. Any Credentialed Provider deficiencies will be addressed through pertinent education and training, re- education and/or referral for confidential peer review through the medical staff.	

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	presence of a current informed consent and to confirm that the patient has not revoked the consent. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS approved the Informed Consent for Blood Component Transfusion Policy CLN1115 on June 20, 2019. This plan of correction is also addressed under the Plans s of Correction Tags A 043, and A 131.	The new Informed Consent for Blood Component Transfusion Policy CLN3276 and the associated EHR workflow will be fully implemented once training is complete.		
A 115(F)	F. The Executive Director of Diagnostic Imaging Administration performed a walk-through of the imaging units in the Hospital, including those on units P3 and P4, and assessed their accessibility to the public. The Executive Director of Diagnostic Imaging Administration evaluated needed changes to physical environment to provide personal privacy and dignity for all patients The Vice President of Ambulatory Operations will perform a walk-through of all ambulatory exam room in the Hospital, and assess their accessibility to the public. The Vice President of Ambulatory Operations evaluated needed changes to the physical environment to provide personal privacy and dignity for all patients The following plans of correction are incorporated by reference into this plan: Plan of Correction Tags A 043, and A 143.	F. Units P3 and P4 X-Ray rooms had privacy curtains installed within hours of the CMS visit. Staff in radiology was instructed by the Executive Director of Diagnostic Imaging to use these privacy curtains whenever a patient was present. The Executive Director of Diagnostic Imaging Administration conducted a gap analysis June 18, 2019 on every x-ray room throughout the organization to identify those x-ray rooms that did not have privacy curtains. A work order was created and all curtains will be installed by July 10, 2019. The Vice President of Ambulatory Operations conducted a gap analysis June 18, 2019 on every ambulatory exam room throughout the organization to identify those exam rooms that did not have privacy curtains. A work order was created and all curtains will be installed by July 10, 2019. Ambulatory staff was instructed by the Vice President of Ambulatory Operations to use these privacy curtains whenever a patient was present. Every Diagnostic Imaging and Ambulatory staff will complete a Computer Based Training on patient personal privacy by July 10, 2019	F. 1 month and 3 months following completion of the corrective action plan, a second walk-through of all ambulatory and Diagnostic Imaging areas of the hospital will be conducted by the Vice President of Ambulatory Operations & Chief Facilities Officer. Any rooms in need of action will be identified, and work orders for correction will be submitted and followed up to ensure completion. Ongoing, routine monitoring will be performed by the Vice President of Ambulatory Operations & Chief Facilities Officer. Any rooms in need of action will be identified, and work orders for correction will be submitted and followed up to ensure completion.	F. Vice President of Ambulatory Operations & Chief Facilities Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
		Ambulatory staff on leave must complete the computer based training before attending patients. Education regarding patient personal privacy is included in new employee orientation for all ambulatory and Diagnostic Imaging staff.		
Tag A 131 Patient Rights: Informed Consent	Hospital has developed an acceptable process to ensure the patient's right (or his or her representative as allowed under State law) to make informed decisions regarding his or her care. Hospital ensures that patient's rights include being informed of his or her health status, being involved in care and planning and treatment, and being able to request or refuse treatment.			
A 131	The Hospital has developed an acceptable process to ensure that patients are allowed to make informed decisions regarding their care, including current signed consent forms for transfusion of blood components. An ESC was convened following the CMS hospital survey. The ESC included the Chief Medical Executive, Chief Medical Officer, Chief Operating Officer, Chief Compliance Officer, and Chief Nursing Officer. The ESC made a determination to update the process for blood component transfusions, to ensure patients who receive blood component transfusions receive information and disclosures needed to make informed decisions. An interdisciplinary team, led by the Chief Medical Officer and including the Chief Nursing Officer, Chief Compliance Officer, Associate Vice President (AVP) for Patient Experience, Medical Practice leaders, Nursing leaders, and Information	The Electronic Health Record (EHR) System will be updated to build the workflow for the new informed consent process and will be fully tested by July 10, 2019. The Chief Education Officer and Training Officer in conjunction with the Chief Medical Officer will develop computer-based training, with knowledge assessment on the new Informed Consent for Blood Component Transfusion Policy CLN3276 and the Blood Component Administration and Transfusion Reaction Policy CLN1115 for Credentialed Providers (Physicians, Advanced Practice Nurses and Physician Assistants) who obtain informed consent for, order, administer or manage complications of blood component transfusions, and registered nurses (RNs) who administer blood components. The topics to be addressed in this training will include: adherence to Informed Consent for Blood Component Transfusion Policy CNL3276, which includes ensuring patients receiving transfusions of blood components have current informed consents and receive information and disclosures needed to make informed decision, including risks, benefits and alternatives, and are informed of the right to refuse	Following completion of training and full implementation of the new Informed Consent for Blood Component Transfusion Policy CLN3276 and the associated EHR workflow, a random sample of 93 blood component transfusion records will be audited and analyzed retrospectively each week by OPI to determine adherence to the Informed Consent for Blood Component Transfusion Policy CLN3276. OPI will review the data with the Chief Medical Officer and the Executive Director of Nursing Quality, Safety and Research to develop recommendations for improvement. In collaboration with the Chief Medical Officer and the Executive Director of Nursing Quality, Safety and Research, OPI will submit the information and recommendations for improvement to the ECMS and the QAPI Council monthly for at least 2 months.	Chief Medical Officer Completion Date for specified corrective actions and initiation of training: July 10, 2019.

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	Technology leaders developed a blood component transfusion informed consent policy. The Informed Consent for Blood Component Transfusion Policy CLN3276 requires that patients and/or their representative receiving transfusions of blood components have current informed consents and receive information and disclosures needed to make informed decisions**,** including risks, benefits and alternatives. Specifically, a patient's Informed Consent for Blood Component Transfusion must be renewed (i) every six months, (ii) when a patient signs a consent to receive a new chemotherapy agent, (iii) when a new primary cancer diagnosis is assigned to the patient, and (iv) any other time the Attending Physician or Physician Designee determines that there is a significant deviation from the course of treatment originally discussed with a patient, or there is a change in a patient's condition or diagnosis that would reasonably be expected to alter the original Informed Consent for Blood Component Transfusion. The Executive Owner of the Policy (the Chief Medical Executive) and the Executive Committee of the Medical Staff (ECMS) approved the Informed Consent for Blood Component Transfusion Policy CLN3276 on June 20, 2019. A training program will be developed by an inter-disciplinary team, led by the Chief Education and Training Officer and the Chief Medical Officer, to develop curriculum and implement training for	treatments through the opportunity to revoke their consent. In addition, training will be provided on the time frame and circumstances for expiration of blood component transfusion consent thereby ensuring patients will have repeated consent after reassessment. Training will also address nursing documentation to confirm the presence of a current informed consent prior to each episode of blood component administration, and to confirm that the patient has not revoked the consent in accordance with the Blood Component Administration and Transfusion Reaction Policy CLN1115. The EHR workflow will be incorporated into the training program. The training program will be developed by July 10, 2019. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions and RNs who administer blood components will receive mandatory computer-based training developed by the Chief Education Officer and Training Officer in conjunction with the Chief Medical Officer. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood components but are on leave must complete the training before attending patients. Education regarding Informed Consent for Blood Component Transfusion Policy CNL3276 and the Blood Component Administration and Transfusion Reaction Policy CLN1115 will be included in the on-boarding process for new Credentialed Providers who order blood components. RNs who administer blood components and are on leave must complete the computer based training	After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a quarterly summation to the ELT and the Governing Body. The Hospital will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate. Any Credentialed Provider deficiencies will be addressed through pertinent education and training, re- education and/or referral for confidential peer review through the medical staff.	

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	Credentialed Providers (Physicians, Advanced Practice Nurses and Physician Assistants) who obtain informed consent for, order, administer or manage complications of blood component transfusions and registered nurses (RNs) who administer blood component transfusions. The training program will be developed by July 10, 2019. The Blood Component Administration and Transfusion Reaction Policy CLN1115 was amended to require nursing documentation to confirm the presence of a current informed consent and to confirm that the patient has not revoked the consent. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS approved the Informed Consent for Blood Component Transfusion Policy CLN1115 on June 20, 2019. This plan of correction is also addressed under the Plans s of Correction Tags A 043, and A 131.	before attending patients. Education regarding compliance with Informed Consent for Blood Component Transfusion Policy CLN3276 and the Blood Component Administration and Transfusion Reaction Policy CLN1115 is included in new employee orientation for all RN staff who administer blood components. Training for the new Informed Consent for Blood Component Transfusion Policy CLN3276 for Hospital's approximately 4,300 Credentialed Providers and RNs who obtain informed consent for, order, administer or manage complications of blood component transfusions will be initiated by July 10, 2019. Hospital will complete the training by July 16, 2019. The new Informed Consent for Blood Component Transfusion Policy CLN3276 and the associated EHR workflow will be fully implemented once training is complete.		
Tag A 143 Patient Rights: Personal Privacy	Hospital ensures the patient's right to personal personal privacy.			
A 143	The Executive Director of Diagnostic Imaging Administration performed a walk-through of the imaging units in the Hospital, including those on units P3 and P4, and assessed their accessibility to the	Units P3 and P4 X-Ray rooms had privacy curtains installed within hours of the CMS visit. Staff in radiology was instructed by the Executive Director of Diagnostic Imaging to use these privacy curtains whenever a patient was present.	1 month and 3 months following completion of the corrective action plan, a second walk-through of all ambulatory and Diagnostic Imaging areas of the hospital will be conducted by the Vice	Vice President of Ambulatory Operations & Chief Facilities Officer

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	public. The Executive Director of Diagnostic Imaging Administration evaluated needed changes to physical environment to provide personal privacy and dignity for all patients. The Vice President of Ambulatory Operations will perform a walk-through of all ambulatory exam room in the Hospital, and assess their accessibility to the public. The Vice President of Ambulatory Operations evaluated needed changes to the physical environment to provide personal privacy and dignity for all patients. The following plans of correction are incorporated by reference into this plan: Plan of Correction Tags A 043, and A 115(F).	The Executive Director of Diagnostic Imaging Administration conducted a gap analysis June 18, 2019 on every x-ray room throughout the organization to identify those x-ray rooms that did not have privacy curtains. A work order was created and all curtains will be installed by July 10, 2019. The Vice President of Ambulatory Operations conducted a gap analysis June 18, 2019 on every ambulatory exam room throughout the organization to identify those exam rooms that did not have privacy curtains. A work order was created and all curtains will be installed by July 10, 2019. Ambulatory staff was instructed by the Vice President of Ambulatory Operations to use these privacy curtains whenever a patient was present. Every Diagnostic Imaging and Ambulatory staff will complete a Computer Based Training on patient personal privacy by July 10, 2019. Ambulatory staff on leave must complete the computer based training before attending patients. Education regarding patient personal privacy is included in new employee orientation for all ambulatory and Diagnostic Imaging staff.	President of Ambulatory Operations & Chief Facilities Officer. Any rooms in need of action will be identified, and work orders for correction will be submitted and followed up to ensure completion. Ongoing, routine monitoring will be performed by the Vice President of Ambulatory Operations & Chief Facilities Officer. Any rooms in need of action will be identified, and work orders for correction will be submitted and followed up to ensure completion.	Completion Date: July 10, 2019
Tag A 144 Patient Rights: Care in Safe Setting	Hospital ensures patients have the right to care in a safe setting. Specifically, Hospital ensures that: 1. blood component transfusions are administered in accordance with Hospital's policy/procedures and acceptable nursing standards; 1.A. nurses continually assess patients during transfusions of blood components, in accordance with Hospital policy; 1.B. nurses notify the physician of changes in vital signs and condition of patients receiving transfusions of blood components, in accordance with Hospital policy; and 2. Hand-Off Communication are performed in transferring a patient with an infectious disease from a patient unit to the operating room, and Contact isolation precautions for safe care are implemented.			
A 144(1)	Hospital ensures that blood component transfusions are administered in accordance with Hospital's	The Associate Director of G9 (Pediatrics) implemented immediate individualized one on one training for the two Pediatric RNs who cared for Patient #34 as	A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by	Chief Operating Officer

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	policy/procedures and acceptable nursing standards. A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including the CMS/CLIA Steering Committee, members of the Transfusion and Patient Blood Management Committee, the Multidisciplinary Clinical Policies and Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and Transfusion Reaction Policy CLN1115. As part of this review over 6,000 patient charts who received blood transfusions were reviewed. A training program was developed by an inter-disciplinary team, including a transfusion medicine faculty member. This team was led by the Executive Director of Nursing, Professional Practice, Strategy and Execution and the Chief Education and Training Officer to develop curriculum and implement training for Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions and registered nurses (RN) who administer blood components pursuant to the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes enhanced nursing standards for administering and monitoring blood components. The hospital nurse training "Blood Component Administration Competency" has been updated to include the following transfusion reaction symptoms: dry,	follows: Nurse-Day Shift: Trained 12/7/18 and 12/31/18. Training included: • Coached on the escalation of concerns • Coached on appropriate documentation of escalation of concerns/provider notification • Nursing practice when carrying out the plan of care; prioritizing interventions • Reviewed gaps in documentation related to hand-off documentation when the patient leaves the unit Nurse- Night Shift- Trained 12/20/18. Training included: • Gaps in vital sign monitoring and documentation for blood component administration • Reviewed signs and symptoms of reactions • Coached on appropriate documentation of escalation of concerns/provider notification • Reviewed institutional policy (CLN1115). RNs who administer blood components received educational information delivered in person by unit nursing leadership (Associate Directors, Nurse Managers, or Clinical Nurse Leaders) starting May 16, 2019 and completed by May 24, 2019. The topics addressed included adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, as supported by ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, acceptable nursing standards for assessment, recognition, responding, and reporting symptoms of suspected transfusion reactions. RNs who administer blood components completed mandatory computer based training with knowledge assessment starting May 17, 2019 to be completed by July 10, 2019. The topics addressed within the computer based training on the Blood Component	the OPI to determine adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115 for vital signs and monitoring, that orders specify the duration for the transfusion, and the actual duration of the transfusion. OPI reviews the data with the Executive Director of Nursing Quality, Safety and Research, and the Laboratory Medicine Quality and Safety Officer to develop recommendations for improvement. In collaboration with the Executive Director of Nursing Quality, Safety and Research and the Laboratory Medicine Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and Patient Blood Management Committee, the ECMS, and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Hospital will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate.	Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	flushed skin, pain in the abdomen and extremities, vomiting and bloody diarrhea. The training also addresses signs and symptoms of transfusion associated circulatory overload. Completed May 17, 2019. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was published on May 19, 2019. Under the revised policy, nursing staff are to take the patient's vital signs prior to initiating the transfusion, 15 minutes into the transfusion, hourly from the start of the transfusion through completion of the transfusion, and at completion of the transfusion. They are required to assess the patient for signs and symptoms of transfusion reaction and document their observations hourly through completion of the transfusion, and at completion of the transfusion. The Electronic Health Record (EHR) includes a list of the symptoms of a transfusion reaction. If the nurse selects yes, the EHR generates a checklist of the symptoms allowing the nurse to select the symptoms that are present. To ensure RNs administer blood components in accordance with Hospital policy and acceptable nursing standards: (1) The Blood Component Administration and Transfusion Reaction Policy CLN1115 was further modified to require that blood	Administration and Transfusion Reaction Policy CLN1115, which includes increased monitoring of vital sign and patient assessment, recognizing, responding and reporting transfusion reactions. Material was also reviewed regarding delivering patient education for participation in their care while receiving blood components. Additional training will be conducted regarding the changes to the EHR Blood Component Order Sets, the modifications to the Blood Component Administration and Transfusion Reaction Policy CLN1115 (including the use of volumetric pumps, orders to include the duration of the transfusion, and definitions of hypotension and fever, as described in ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction), and the Stop the Line for Patient Safety Policy CLN1185, by July 10, 2019. RNs on leave who transfuse blood components must complete training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the enhanced nursing standards for administering and monitoring blood component transfusions, and the Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new RNs who transfuse blood components. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions will complete the computer based training as outlined above by July 10, 2019. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood components and are on leave must complete the computer based training before attending	Any Credentialed Provider deficiencies will be addressed through pertinent education and training, re-education and/or referral for confidential peer review through the medical staff.	

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	components are administered via volumetric pump to ensure the duration of the transfusion is in accordance with the physician's orders. (Accordingly, blood components will not be administered via "gravity" flow). The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was approved on June 20, 2019. (2) Based on the National Patient Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol, published April 2018 by the Centers for Disease Control the Blood Component Administration and Transfusion Reaction Policy CLN1115 will be amended to include the definitions of hypotension and fever, by July 10, 2019. ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, which supports CLN1115, will be revised to address the hypotension and fever parameters by July 10, 2019. (3) EHR Physician Blood Component Order Set was modified to require duration of blood component transfusion. A Credentialed Provider must specify the duration of the blood component transfusion in order to complete the blood component order (hard stop). This change will be effective by July 10, 2019. (4) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone	patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new Credentialed Providers. A reminder communication will be sent to all nursing staff who administer and monitor transfusions regarding the process for reporting a suspected transfusion reaction, by July 10, 2019.		

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	to stop the line for an incomplete, conflicting or unclear order or in the event of a suspected transfusion reaction. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS approved the updated Stop the Line for Patient Safety Policy CLN1185, which was approved on June 20, 2019. Further training was developed on the EHR Blood Component Order Sets, and the modifications to the Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185. The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20, 2019. Following a 2-4 week prospective pilot in 3 areas where transfusions are administered (Phase 2), the Hemovigilance Unit will track the vital signs of each patient receiving transfusion services in real time (Phase 3). These vital signs will be reviewed by an RN under the supervision of an Advanced Practice Provider (APP) or physician 24/7 to complement the monitoring being provided at the bedside.			

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	The real time monitoring will also weight the vital signs and assign a risk number for each patient that is updated in real time, highlighting patients exhibiting potential signs of a reaction. Signs of a reaction will be referred to a member of the transfusion medicine practice. In addition to the monitoring being done by nursing under this POC, the Hemovigilance Unit will also review potential false negatives on an ongoing basis and report to the Transfusion and Patient Blood Management Committee. We are not formally submitting Phase 2 and 3 as part of our corrective action as these require a significant time investment to operationalize it across the hospital but we wanted CMS to be aware of its development as proof of our commitment to being an industry leader in developing new, innovative approaches to delivering the highest level of care. This plan of correction is also addressed under the Plans of Correction Tags A 043, A 115, A 385, and A 409.			
A 144(1)(A)	The Hospital ensures that nurses continually assess patients during transfusion of blood components. A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including the CMS/CLIA Steering Committee, members of the Transfusion and Patient Blood Management Committee, the Multidisciplinary Clinical Policies and Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and	The Associate Director of G9 (Pediatrics) implemented immediate individualized one on one training for the two Pediatric RNs who cared for Patient #34 as follows: Nurse-Day Shift: Trained 12/7/18 and 12/31/18. Training included: • Coached on the escalation of concerns • Coached on appropriate documentation of escalation of concerns/provider notification • Nursing practice when carrying out the plan of care; prioritizing interventions • Reviewed gaps in documentation related to	A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by the OPI to determine adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115 for the for vital signs and monitoring. OPI reviews the data with the Executive Director of Nursing Quality, Safety and Research, and the Laboratory Medicine Quality and Safety Officer to develop recommendations for improvement. In collaboration with the Executive	Chief Operating Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	Transfusion Reaction Policy CLN1115. As part of this review over 6,000 patient charts who received blood transfusions were reviewed. A training program was developed by an inter-disciplinary team, including a transfusion medicine faculty member. This team was led by the Executive Director of Nursing, Professional Practice, Strategy and Execution and the Chief Education and Training Officer to develop curriculum and implement training for Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions and registered nurses (RN) who administer blood components pursuant to the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes enhanced nursing standards for administering and monitoring blood components. The hospital nurse training "Blood Component Administration Competency" has been updated to include the following transfusion reaction symptoms: dry, flushed skin, pain in the abdomen and extremities, vomiting and bloody diarrhea. The training also addresses signs and symptoms of transfusion associated circulatory overload. Completed May 17, 2019. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was published on	hand-off documentation when the patient leaves the unit RNs who administer blood components received educational information delivered in person by unit nursing leadership (Associate Directors, Nurse Managers, or Clinical Nurse Leaders) starting May 16, 2019 and completed by May 24, 2019. The topics addressed included adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, as supported by ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, acceptable nursing standards for continual assessment, recognition, responding, and reporting symptoms of suspected transfusion reactions. RNs who administer blood components completed mandatory computer based training with knowledge assessment starting May 17, 2019 to be completed by July 10, 2019. The topics addressed within the computer based training on the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes increased monitoring of vital sign and patient assessment, recognizing, responding and reporting transfusion reactions. Material was also reviewed regarding delivering patient education for participation in their care while receiving blood components. Additional training will be conducted regarding the changes to the Blood Component Administration and Transfusion Reaction Policy CLN1115 (including definitions of hypotension and fever, as described in ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction), and the Stop the Line for Patient Safety Policy CLN1185, by July 10, 2019. RNs on leave who transfuse blood components must complete training before attending patients.	Director of Nursing Quality, Safety and Research and the Laboratory Medicine Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and Patient Blood Management Committee, the ECMS, and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Hospital will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate. Any Credentialed Provider deficiencies will be addressed through pertinent education and training, re-education and/or referral for confidential peer review through the medical staff.	

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	May 19, 2019. Under the revised policy, nursing staff are to take the patient's vital signs prior to initiating the transfusion, 15 minutes into the transfusion, hourly from the start of the transfusion through completion of the transfusion, and at completion of the transfusion. They are required to assess the patient for signs and symptoms of transfusion reaction and document their observations hourly through completion of the transfusion, and at completion of the transfusion. The Electronic Health Record (EHR) includes a list of the symptoms of a transfusion reaction. If the nurse selects yes, the EHR generates a checklist of the symptoms allowing the nurse to select the symptoms that are present. To ensure RNs administer blood components in accordance with Hospital policy and acceptable nursing standards: (1) Based on the National Patient Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol, published April 2018 by the Centers for Disease Control the Blood Component Administration and Transfusion Reaction Policy CLN1115 will be amended to include the definitions of hypotension and fever, by July 10, 2019. ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, which supports CLN1115, will be revised to address the hypotension and fever	Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the enhanced nursing standards for administering and monitoring blood component transfusions, and the Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new RNs who transfuse blood components. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions will complete the computer based training as outlined above by July 10, 2019. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood components and are on leave must complete the computer based training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new Credentialed Providers.		

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	parameters by July 10, 2019. (2) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone to stop the line for an incomplete, conflicting or unclear order or in the event of a suspected transfusion reaction. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS approved the updated Stop the Line for Patient Safety Policy CLN1185, which was approved on June 20, 2019. Further training was developed on the modifications to the Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185. The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20, 2019. Following a 2-4 week prospective pilot in 3 areas where transfusions are administered (Phase 2), the Hemovigilance Unit will track the vital signs of each patient receiving transfusion services in real time (Phase 3). These vital signs will be reviewed by an RN under the supervision			

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	of an APP or physician 24/7 to complement the monitoring being provided at the bedside. The real time monitoring will also weight the vital signs and assign a risk number for each patient that is updated in real time, highlighting patients exhibiting potential signs of a reaction. Signs of a reaction will be referred to a member of the transfusion medicine practice. In addition to the monitoring being done by nursing under this POC, the Hemovigilance Unit will also review potential false negatives on an ongoing basis and report to the Transfusion and Patient Blood Management Committee. We are not formally submitting Phase 2 and 3 as part of our corrective action as these require a significant time investment to operationalize it across the hospital but we wanted CMS to be aware of its development as proof of our commitment to being an industry leader in developing new, innovative approaches to delivering the highest level of care. This plan of correction is also addressed under the Plans of Correction Tags A 115, A 144, A 385, and A 409.			
A 144(1)(B)	Hospital ensures that nurses notify the Credentialed Providers of changes in vital signs and condition of patients receiving transfusions of blood components as required under the Hospital policy. A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including the CMS/CLIA Steering Committee, members of the Transfusion and Patient	The Associate Director of G9 (Pediatrics) implemented immediate individualized one on one training for the two Pediatric RNs who cared for Patient #34 as follows: Nurse-Day Shift: Trained 12/7/18 and 12/31/18. Training included: • Coached on the escalation of concerns • Coached on appropriate documentation of escalation of concerns/provider notification	A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by the OPI to determine adherence to (1) Blood Component Administration and Transfusion Reaction Policy CLN1115, including reporting to and consulting with the Credentialed Provider and the Transfusion Medicine Physician for suspected transfusion reactions, and (2) Stop the Line for Patient Safety Policy	Chief Operating Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	Blood Management Committee, the Multidisciplinary Clinical Policies and Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and Transfusion Reaction Policy CLN1115. As part of this review over 6,000 patient charts who received blood transfusions were reviewed. A training program was developed by an inter-disciplinary team, including a transfusion medicine faculty member. This team was led by the Executive Director of Nursing, Professional Practice, Strategy and Execution and the Chief Education and Training Officer to develop curriculum and implement training for Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions and registered nurses (RN) who administer blood components pursuant to the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes enhanced nursing standards for administering and monitoring blood components. The hospital nurse training "Blood Component Administration Competency" has been updated to include the following transfusion reaction symptoms: dry, flushed skin, pain in the abdomen and extremities, vomiting and bloody diarrhea. The training also addresses signs and symptoms of transfusion associated circulatory overload. Completed May 17, 2019.	• Nursing practice when carrying out the plan of care; prioritizing interventions Reviewed gaps in documentation related to hand-off documentation when the patient leaves the unit Nurse- Night Shift- Trained 12/20/18. Training included: • Gaps in vital sign monitoring and documentation for blood component administration • Reviewed signs and symptoms of reactions • Coached on appropriate documentation of escalation of concerns/provider notification • Reviewed institutional policy (CLN1115). RNs who administer blood components received educational information delivered in person by unit nursing leadership (Associate Directors, Nurse Managers, or Clinical Nurse Leaders) starting May 16, 2019 and completed by May 24, 2019. The topics addressed included adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, as supported by ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, acceptable nursing standards for assessment, recognition, responding, and reporting symptoms of suspected transfusion reactions. RNs who administer blood components completed mandatory computer based training with knowledge assessment starting May 17, 2019 to be completed by July 10, 2019. The topics addressed within the computer based training on the Blood Component Administration and Transfusion Reaction Policy CLN1115, included increased monitoring of vital sign and patient assessment, recognizing, responding and reporting transfusion reactions to and consulting with the Credentialed Provider and the Transfusion Medicine Physician, and clarifying physician orders. Material was also reviewed regarding delivering	CLN1185, to stop the line in the event of a suspected transfusion reaction or an incomplete, conflicting or unclear order. OPI reviews the data with the Executive Director of Nursing Quality, Safety and Research, and the Laboratory Medicine Quality and Safety Officer to develop recommendations for improvement. In collaboration with the Executive Director of Nursing Quality, Safety and Research and the Laboratory Medicine Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and Patient Blood Management Committee, the ECMS, and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Hospital will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate. Any Credentialed Provider deficiencies will be addressed through pertinent	

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was published on May 19, 2019. Under the revised policy, nursing staff are to take the patient's vital signs prior to initiating the transfusion, 15 minutes into the transfusion, hourly from the start of the transfusion through completion of the transfusion, and at completion of the transfusion. They are required to assess the patient for signs and symptoms of transfusion reaction and document their observations hourly through completion of the transfusion and at completion of the transfusion. The Electronic Health Record (EHR) includes a list of the symptoms of a transfusion reaction. If the nurse selects yes, the EHR generates a checklist of the symptoms allowing the nurse to select the symptoms that are present. To ensure RNs notify the Credentialed Providers of condition of patients receiving transfusions of blood components as required under the Hospital policy: (1) Based on the National Patient Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol, published April 2018 by the Centers for Disease Control the Blood Component Administration and Transfusion Reaction Policy CLN1115 will be amended to include the definitions of hypotension and fever, by July 10, 2019.	patient education for participation in their care while receiving blood components. Additional training will be conducted regarding the changes to the Blood Component Administration and Transfusion Reaction Policy CLN1115 (including definitions of hypotension and fever, reporting suspected transfusion reactions to and consulting with the Credentialed Provider and the Transfusion Medicine Physician), and the Stop the Line for Patient Safety Policy CLN1185, by July 10, 2019. RNs on leave who transfuse blood components must complete training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the enhanced nursing standards for administering and monitoring blood component transfusions, Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new RNs who transfuse blood components. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions will complete the computer based training as outlined above by July 10, 2019. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood components and are on leave must complete the computer based training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 is included in the on-boarding process for new Credentialed Providers.	education and training, re-education and/or referral for confidential peer review through the medical staff.	

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, which supports CLN1115, will be revised to address the hypotension and fever parameters by July 10, 2019. (2) The Blood Component Administration and Transfusion Reaction Policy CLN1115 was further modified to require that the Transfusion Medicine Physician is consulted regarding suspected blood component transfusion reactions. (3) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone to stop the line for an incomplete, conflicting or unclear order or in the event of a suspected transfusion reaction. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS approved the updated Stop the Line for Patient Safety Policy CLN1185, which was approved on June 20, 2019. Further training was developed on the modifications to the Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185. The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having			

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20, 2019. The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20, 2019. Following a 2-4 week prospective pilot in 3 areas where transfusions are administered (Phase 2), the Hemovigilance Unit will track the vital signs of each patient receiving transfusion services in real time (Phase 3). These vital signs will be reviewed by an RN under the supervision of an APP or physician 24/7 to complement the monitoring being provided at the bedside. The real time monitoring will also weight the vital signs and assign a risk number for each patient that is updated in real time, highlighting patients exhibiting potential signs of a reaction. Signs of a reaction will be referred to a member of the transfusion medicine practice. In addition to the monitoring being done by nursing under this POC, the Hemovigilance Unit will also review potential false negatives on an ongoing basis and report to the Transfusion and Patient Blood			

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	Management Committee. We are not formally submitting Phase 2 and 3 as part of our corrective action as these require a significant time investment to operationalize it across the hospital but we wanted CMS to be aware of its development as proof of our commitment to being an industry leader in developing new, innovative approaches to delivering the highest level of care. This plan of correction is also addressed under the Plans of Correction Tags A 043, A 115, A 385, and A 409.			
A 144(2)	Hand-Off Communications are performed and documented in transferring a patient with isolation precaution orders from one patient location to another to ensure that isolation precautions for safe care are implemented. Nursing leadership reviewed Hand-Off Communication Policy CLN0513 in relation to transfers within Hospital, by June 19, 2019. The Executive Director of Clinical Informatics approved a modification to the EHR Hand-Off Communication documentation for nursing to include isolation precautions. A new flow sheet row will serve as the transferring RN's attestation that the isolation status was communicated to the receiving health care provider. The Executive Director of Nursing, Professional Practice, Strategy and Execution in collaboration with the Director of Education developed and will	RNs who provide hand-off communication for patients transferring within Hospital will receive education and training with nurse leadership (Associate Director, nurse manager, clinical nurse leaders and educators) to be completed by July 10, 2019. The topics addressed during the training will emphasize isolation precaution information, adherence to Hand-Off Communication Policy CLN 0513, and documentation and modification enhancements to EHR to include attestation of isolation precautions. RNs on leave who provide hand-off communication for patients transferring within Hospital must complete the training before attending patients Education regarding isolation precaution information, adherence to Hand-Off Communication Policy CLN 0513, documentation and the EHR that includes attestation of isolation precautions will be included in the on-boarding process for new RNs who provide hand-off communication for patients transferring within Hospital.	The Hospital will prepare a report reflecting all isolation inpatients with a permanent or temporary hand-off to assess whether the RN attestation of hand-off and isolation precaution was communicated and documented. The report is reviewed weekly by the Executive Directors of Nursing team and the Chief Nursing Officer, who may recommend and implement any appropriate changes. The report will be submitted to the QAPI Council monthly for the initial quarter. After the first quarter, QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. Monitoring and reporting will continue until 100% compliance is documented for two consecutive months. The QAPI Council will review the information, and may make	Chief Nursing Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	implement educational training specifically addressing hand-off communication and documentation related to isolation precautions for patient transfers within Hospital in accordance with Hand-Off Communication Policy CLN 0513 and the new documentation. This plan of correction is also addressed under the Plans of Correction Tags A 043, A 115.		recommendations for further improvement, and provide at least a summation to the ELT and the Governing Body at least quarterly. The Hospital will address any deficiencies with the individual RN through pertinent training, re-education and/or disciplinary action, as appropriate.	
Tag A 263 QAPI	Hospital has developed, has implemented and maintains an effective, ongoing, hospital-wide, data-driven Quality Assessment and Performance Improvement (QAPI) program. The hospital's Governing Body ensures that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contractor arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital maintains demonstrable evidence of its QAPI program for review by CMS.			
A 263	Hospital adopted a formal, effective, ongoing, hospital-wide and data-driven QAPI Program that reflects the complexity of the Hospital's structure and services. The QAPI Program includes all Hospital departments and services, including services furnished under contract or arrangement. The Chair of the ECMS, representatives of the ELT and Governing Body will approve the updated QAPI Program on June 27, 2019. The Governing Body has established the Quality Assessment and Performance Improvement Council (QAPI Council) on June 13, 2019, as the overall coordinating body for hospital-wide quality and safety efforts across the organization. The QAPI Council is responsible to provide regular reports to the Governing Body and the ELT on the results and effectiveness of the QAPI Program. The Governing Body	The QAPI Program is supported by the Office of Performance Improvement, which reports to the Chief Operating Officer. The Office of Performance Improvement provides support for the QAPI Program through three separate departments (Patient Safety and Accreditation; Quality Measurement; and Healthcare Systems Engineering). The Chief Patient Safety Officer, the Chief Value and Quality Officer and the Chief Patient Experience Officer, covering the Hospital departments, will report to the QAPI Council all quality assessment, quality improvement, and other quality indicator data described in the QAPI Program in accordance with the QAPI Council meeting schedule. These officers will report immediate or significant quality concerns on an ad hoc basis to the QAPI Council. The QAPI Council Chairs will report immediately to the ELT and the Governing Body. Ad hoc meetings will be scheduled at the request of the QAPI Council Chairs. The frequency for each department, committee and contracted service is documented in the reporting cadence. The QAPI Council reports to the ELT and the Governing Body at least 10 times a year, as noted.	The Chief Operating Officer and Chief Medical Executive will jointly monitor the QAPI Program on a monthly basis for the initial 6 months to: i. Ensure the QAPI Council is meeting at least 10 times per year, ii. Document meeting minutes iii. Focus on the indicators as directed by the Governing Body related to improved health outcomes and prevention and reduction of medical errors, and otherwise complying with the QAPI Program. iv. Ensure the QAPI program is hospital-wide. v. Ensure reporting to the Governing Body in accordance with the QAPI Program. This monitoring will occur until 100% compliance of the above noted criteria is achieved for 6 consecutive months and annually thereafter. The results are reported to the ELT and the Governing Body.	Chief Operating Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	appointed the QAPI Council Chairs on June 13, 2019. The QAPI Council reviews quality indicator data, identifies gaps, and is accountable for successful implementation of action plans to improve health outcomes and prevent and reduce medical errors from all clinical departments in the Hospital. The QAPI Council facilitates creating, promoting and maintaining a culture of safety and quality throughout the Hospital as a result of its actions. The QAPI Council provides the infrastructure for leaders to use data and information to guide decisions and to understand variation in the performance of processes supporting safety, quality/outcomes and patient experience. The QAPI Program includes a reporting cadence for the departments, committees and contracted services that report to the QAPI Council. The QAPI Council meets at least 10 times per year, takes minutes of all reviews and actions and provides feedback to appropriate committees. The QAPI Council reports to the ELT and the Governing Body at least 10 times per year. The QAPI Council provides support for the hospital-wide systems to collect, analyze, report and utilize meaningful, accurate data throughout the Hospital. For Performance Improvement, the QAPI Council utilizes a dedicated focus on data collection and reporting, and is accountable for the successful implementation of analysis and action planning to impact areas and processes that are high-risk, high-volume and problem-prone throughout the Hospital.	The Governing Body, ELT members, QAPI Council members, QAPI Council Subcommittee members and Patient Safety Quality Officers will receive mandatory education on the QAPI Program directed by the Chief Operating Officer, by July 10, 2019. Topics addressed during the education include CMS and Hospital expectations for QAPI activities, new responsibilities for each individual and new quality-related reporting structure. Any ELT members, QAPI Council members, QAPI Council Subcommittee members and Patient Safety Quality Officers on leave (FMLA or vacation) must complete the education before resuming quality responsibilities. Education regarding the QAPI Program is included in the on-boarding process for new ELT members, QAPI Council members, QAPI Council Subcommittee members and Patient Safety Quality Officers.	The ELT as directed by the Governing Body will address any deficiencies with the QAPI Council, as appropriate. The Governing Body has directed priority measures for the QAPI Program, to include blood component transfusion. The Governing Body will perform periodic evaluation of the metrics to ensure meaningful and relevant measures related to safety, quality/outcomes and patient experience.	

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	The Governing Body has directed the ELT to facilitate the oversight of the QAPI Council and the evaluation of data and actions taken to support safety, quality/outcomes and patient experience. The QAPI Council reports to the ELT at least 10 times a year and the Governing body chairs ELT to effectuate the goals of the QAPI Program and ensure that the QAPI Program reflects the complexity of the Hospital's organization and services, including services furnished under contract or arrangement, and focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The Governing Body and the ELT provides oversight and ensures that the QAPI program reviews each of the alleged deficiencies in the 2567 that impacts or could impact quality of care. The Hospital maintains and demonstrates evidence of its QAPI Program for review by CMS. The following plan of correction is incorporated by reference into this Plan: Plan of Correction Tag A-043.			
Tag A 385 Nursing Services	The Hospital has an organized nursing service that provides 24-hour nursing services. The nursing services are furnished or supervised by a registered nurse.			
A 385(A)	A. Hospital ensures that blood component transfusions are administered in accordance with Hospital's policy/procedures and acceptable nursing	A. The Associate Director of G9 (Pediatrics) implemented immediate individualized one on one training for the two Pediatric RNs who cared for Patient #34 as follows:	A. A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by the OPI to determine adherence	A. Chief Nursing Officer Completion Date:

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	standards. A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including the CMS/CLIA Steering Committee, members of the Transfusion and Patient Blood Management Committee, the Multidisciplinary Clinical Policies and Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and Transfusion Reaction Policy CLN1115. As part of this review over 6,000 patient charts who received blood transfusions were reviewed. A training program was developed by an inter-disciplinary team, including a transfusion medicine faculty member. This team was led by the Executive Director of Nursing, Professional Practice, Strategy and Execution and the Chief Education and Training Officer to develop curriculum and implement training for Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions and registered nurses (RN) who administer blood components pursuant to the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes enhanced nursing standards for administering and monitoring blood components. The hospital nurse training "Blood Component Administration Competency" has been updated to include the following transfusion reaction symptoms: dry, flushed skin, pain in the abdomen and	Nurse-Day Shift: Trained 12/7/18 and 12/31/18. Training included: • Coached on the escalation of concerns • Coached on appropriate documentation of escalation of concerns/provider notification • Nursing practice when carrying out the plan of care; prioritizing interventions • Reviewed gaps in documentation related to hand-off documentation when the patient leaves the unit Nurse- Night Shift- Trained 12/20/18. Training included: • Gaps in vital sign monitoring and documentation for blood component administration • Reviewed signs and symptoms of reactions • Coached on appropriate documentation of escalation of concerns/provider notification • Reviewed institutional policy (CLN1115). RNs who administer blood components received educational information delivered in person by unit nursing leadership (Associate Directors, Nurse Managers, or Clinical Nurse Leaders) starting May 16, 2019 and completed by May 24, 2019. The topics addressed included adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, as supported by ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, acceptable nursing standards for assessment, recognition, responding, and reporting symptoms of suspected transfusion reactions. RNs who administer blood components completed mandatory computer based training with knowledge assessment starting May 17, 2019 to be completed by July 10, 2019. The topics addressed within the computer based training on the Blood Component Administration and Transfusion Reaction Policy	to Blood Component Administration and Transfusion Reaction Policy CLN1115 for vital signs and monitoring, that orders specify the duration for the transfusion, and the actual duration of the transfusion. OPI reviews the data with the Executive Director of Nursing Quality, Safety and Research, and the Laboratory Medicine Quality and Safety Officer to develop recommendations for improvement. In collaboration with the Executive Director of Nursing Quality, Safety and Research and the Laboratory Medicine Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and Patient Blood Management Committee, the ECMS, and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Hospital will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate.	July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	extremities, vomiting and bloody diarrhea. The training also addresses signs and symptoms of transfusion associated circulatory overload. Completed May 17, 2019. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was published on May 19, 2019. Under the revised policy, nursing staff are to take the patient's vital signs prior to initiating the transfusion, 15 minutes into the transfusion, hourly from the start of the transfusion through completion of the transfusion, and at completion of the transfusion. They are required to assess the patient for signs and symptoms of transfusion reaction and document their observations hourly through completion of the transfusion, and at completion of the transfusion. The Electronic Health Record (EHR) includes a list of the symptoms of a transfusion reaction. If the nurse selects yes, the EHR generates a checklist of the symptoms allowing the nurse to select the symptoms that are present. To ensure RNs administer blood components in accordance with Hospital policy and acceptable nursing standards: (1) The Blood Component Administration and Transfusion Reaction Policy CLN1115 was further modified to require that blood components are administered via	CLN1115, which includes increased monitoring of vital sign and patient assessment, recognizing, responding and reporting transfusion reactions. Material was also reviewed regarding delivering patient education for participation in their care while receiving blood components. Additional training will be conducted regarding the changes to the EHR Blood Component Order Sets, the modifications to the Blood Component Administration and Transfusion Reaction Policy CLN1115 (including the use of volumetric pumps, orders to include the duration of the transfusion, and definitions of hypotension and fever, as described in ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction), and the Stop the Line for Patient Safety Policy CLN1185, by July 10, 2019. RNs on leave who transfuse blood components must complete training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the enhanced nursing standards for administering and monitoring blood component transfusions, and the Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new RNs who transfuse blood components. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions will complete the computer based training as outlined above by July 10, 2019. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood components and are on leave must complete the computer based training before attending patients.	Any Credentialed Provider deficiencies will be addressed through pertinent education and training, re-education and/or referral for confidential peer review through the medical staff.	

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	volumetric pump to ensure the duration of the transfusion is in accordance with the physician's orders. (Accordingly, blood components will not be administered via "gravity" flow). The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was approved on June 20, 2019. (2) Based on the National Patient Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol, published April 2018 by the Centers for Disease Control the Blood Component Administration and Transfusion Reaction Policy CLN1115 will be amended to include the definitions of hypotension and fever, by July 10, 2019. ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, which supports CLN1115, will be revised to address the hypotension and fever parameters by July 10, 2019. (3) EHR Physician Blood Component Order Set was modified to require duration of blood component transfusion. A Credentialed Provider must specify the duration of the blood component transfusion in order to complete the blood component order (hard stop). This change will be effective by July 10, 2019. (4) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone to stop the line for an incomplete,	Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new Credentialed Providers. A reminder communication will be sent to all nursing staff who administer and monitor transfusions regarding the process for reporting a suspected transfusion reaction, by July 10, 2019.		

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	conflicting or unclear order or in the event of a suspected transfusion reaction. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS approved the updated Stop the Line for Patient Safety Policy CLN1185, which was approved on June 20, 2019. Further training was developed on the EHR Blood Component Order Sets, and the modifications to the Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185. The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20, 2019. Following a 2-4 week prospective pilot in 3 areas where transfusions are administered (Phase 2), the Hemovigilance Unit will track the vital signs of each patient receiving transfusion services in real time (Phase 3). These vital signs will be reviewed by an RN under the supervision of an Advanced Practice Provider (APP) or physician 24/7 to complement the monitoring being provided at the bedside. The real time monitoring will also weight			

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	the vital signs and assign a risk number for each patient that is updated in real time, highlighting patients exhibiting potential signs of a reaction. Signs of a reaction will be referred to a member of the transfusion medicine practice. In addition to the monitoring being done by nursing under this POC, the Hemovigilance Unit will also review potential false negatives on an ongoing basis and report to the Transfusion and Patient Blood Management Committee. We are not formally submitting Phase 2 and 3 as part of our corrective action as these require a significant time investment to operationalize it across the hospital but we wanted CMS to be aware of its development as proof of our commitment to being an industry leader in developing new, innovative approaches to delivering the highest level of care. This plan of correction is also addressed under the Plans of Correction Tags A 043, A 144, A 115, and A 409.			
A 385(A)(1)	The Hospital ensures that nurses continually assess patients during transfusion of blood components. A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including the CMS/CLIA Steering Committee, members of the Transfusion and Patient Blood Management Committee, the Multidisciplinary Clinical Policies and Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and Transfusion Reaction Policy CLN1115. As	The Associate Director of G9 (Pediatrics) implemented immediate individualized one on one training for the two Pediatric RNs who cared for Patient #34 as follows: Nurse-Day Shift: Trained 12/7/18 and 12/31/18. Training included: • Coached on the escalation of concerns • Coached on appropriate documentation of escalation of concerns/provider notification • Nursing practice when carrying out the plan of care; prioritizing interventions • Reviewed gaps in documentation related to hand-off documentation when the patient	A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by the OPI to determine adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115 for the for vital signs and monitoring. OPI reviews the data with the Executive Director of Nursing Quality, Safety and Research, and the Laboratory Medicine Quality and Safety Officer to develop recommendations for improvement. In collaboration with the Executive Director of Nursing Quality, Safety and	Chief Nursing Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	part of this review over 6,000 patient charts who received blood transfusions were reviewed. A training program was developed by an inter-disciplinary team, including a transfusion medicine faculty member. This team was led by the Executive Director of Nursing, Professional Practice, Strategy and Execution and the Chief Education and Training Officer to develop curriculum and implement training for Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions and registered nurses (RN) who administer blood components pursuant to the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes enhanced nursing standards for administering and monitoring blood components. The hospital nurse training "Blood Component Administration Competency" has been updated to include the following transfusion reaction symptoms: dry, flushed skin, pain in the abdomen and extremities, vomiting and bloody diarrhea. The training also addresses signs and symptoms of transfusion associated circulatory overload. Completed May 17, 2019. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was published on May 19, 2019.	leaves the unit RNs who administer blood components received educational information delivered in person by unit nursing leadership (Associate Directors, Nurse Managers, or Clinical Nurse Leaders) starting May 16, 2019 and completed by May 24, 2019. The topics addressed included adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, as supported by ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, acceptable nursing standards for continual assessment, recognition, responding, and reporting symptoms of suspected transfusion reactions. RNs who administer blood components completed mandatory computer based training with knowledge assessment starting May 17, 2019 to be completed by July 10, 2019. The topics addressed within the computer based training on the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes increased monitoring of vital sign and patient assessment, recognizing, responding and reporting transfusion reactions. Material was also reviewed regarding delivering patient education for participation in their care while receiving blood components. Additional training will be conducted regarding the changes to the Blood Component Administration and Transfusion Reaction Policy CLN1115 (including definitions of hypotension and fever, as described in ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction), and the Stop the Line for Patient Safety Policy CLN1185, by July 10, 2019. RNs on leave who transfuse blood components must complete training before attending patients. Education regarding Blood Component Administration	Research and the Laboratory Medicine Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and Patient Blood Management Committee, the ECMS, and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Hospital will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate. Any Credentialed Provider deficiencies will be addressed through pertinent education and training, re-education and/or referral for confidential peer review through the medical staff.	

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	Under the revised policy, nursing staff are to take the patient's vital signs prior to initiating the transfusion, 15 minutes into the transfusion, hourly from the start of the transfusion through completion of the transfusion, and at completion of the transfusion. They are required to assess the patient for signs and symptoms of transfusion reaction and document their observations hourly through completion of the transfusion, and at completion of the transfusion. The Electronic Health Record (EHR) includes a list of the symptoms of a transfusion reaction. If the nurse selects yes, the EHR generates a checklist of the symptoms allowing the nurse to select the symptoms that are present. To ensure RNs administer blood components in accordance with Hospital policy and acceptable nursing standards: (1) Based on the National Patient Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol, published April 2018 by the Centers for Disease Control the Blood Component Administration and Transfusion Reaction Policy CLN1115 will be amended to include the definitions of hypotension and fever, by July 10, 2019. ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, which supports CLN1115, will be revised to address the hypotension and fever parameters by July 10, 2019.	and Transfusion Reaction Policy CLN1115 and the enhanced nursing standards for administering and monitoring blood component transfusions, and the Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new RNs who transfuse blood components. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions will complete the computer based training as outlined above by July 10, 2019. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood components and are on leave must complete the computer based training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new Credentialed Providers.		

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	(2) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone to stop the line for an incomplete, conflicting or unclear order or in the event of a suspected transfusion reaction. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS approved the updated Stop the Line for Patient Safety Policy CLN1185, which was approved on June 20, 2019. Further training was developed on the modifications to the Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185. The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20, 2019. Following a 2-4 week prospective pilot in 3 areas where transfusions are administered (Phase 2), the Hemovigilance Unit will track the vital signs of each patient receiving transfusion services in real time (Phase 3). These vital signs will be reviewed by an RN under the supervision of an APP or physician 24/7 to complement the monitoring being			

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	provided at the bedside. The real time monitoring will also weight the vital signs and assign a risk number for each patient that is updated in real time, highlighting patients exhibiting potential signs of a reaction. Signs of a reaction will be referred to a member of the transfusion medicine practice. In addition to the monitoring being done by nursing under this POC, the Hemovigilance Unit will also review potential false negatives on an ongoing basis and report to the Transfusion and Patient Blood Management Committee. We are not formally submitting Phase 2 and 3 as part of our corrective action as these require a significant time investment to operationalize it across the hospital but we wanted CMS to be aware of its development as proof of our commitment to being an industry leader in developing new, innovative approaches to delivering the highest level of care. This plan of correction is also addressed under the Plans of Correction Tags A 043, A 144, A 115, and A 409.			
A 385(A)(2)	The Hospital ensures that RNs provide and documented timely, complete and accurate assessments on patients who experienced transfusion reactions. A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including the CMS/CLIA Steering Committee, members of the Transfusion and Patient Blood Management Committee, the Multidisciplinary Clinical Policies and	The Associate Director of G9 (Pediatrics) implemented immediate individualized one on one training for the two Pediatric RNs who cared for Patient #34 as follows: Nurse-Day Shift: Trained 12/7/18 and 12/31/18. Training included: • Coached on the escalation of concerns • Coached on appropriate documentation of escalation of concerns/provider notification • Nursing practice when carrying out the plan of care; prioritizing interventions	A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by the OPI to determine adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115 for the for vital signs and monitoring and documentation in accordance with Nursing Documentation of Patient Care Policy CLN0647. OPI reviews the data with the Executive Director of Nursing Quality, Safety and Research, and the Laboratory Medicine Quality and Safety	Chief Nursing Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and Transfusion Reaction Policy CLN1115. As part of this review over 6,000 patient charts who received blood transfusions were reviewed. A training program was developed by an inter-disciplinary team, including a transfusion medicine faculty member. This team was led by the Executive Director of Nursing, Professional Practice, Strategy and Execution and the Chief Education and Training Officer to develop curriculum and implement training for Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions and registered nurses (RN) who administer blood components pursuant to the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes enhanced nursing standards for administering and monitoring blood components. The hospital nurse training "Blood Component Administration Competency" has been updated to include the following transfusion reaction symptoms: dry, flushed skin, pain in the abdomen and extremities, vomiting and bloody diarrhea. The training also addresses signs and symptoms of transfusion associated circulatory overload. Completed May 17, 2019. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component	• Reviewed gaps in documentation related to hand-off documentation when the patient leaves the unit RNs who administer blood components received educational information delivered in person by unit nursing leadership (Associate Directors, Nurse Managers, or Clinical Nurse Leaders) starting May 16, 2019 and completed by May 24, 2019. The topics addressed included adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, as supported by ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, acceptable nursing standards for continual assessment, recognition, responding, and reporting symptoms of suspected transfusion reactions. RNs who administer blood components completed mandatory computer based training with knowledge assessment starting May 17, 2019 to be completed by July 10, 2019. The topics addressed within the computer based training on the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes increased monitoring of vital sign and patient assessment, recognizing, responding and reporting transfusion reactions. Material was also reviewed regarding delivering patient education for participation in their care while receiving blood components. Additional training will be conducted regarding the changes to the Blood Component Administration and Transfusion Reaction Policy CLN1115 (including definitions of hypotension and fever, as described in ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction), the Stop the Line for Patient Safety Policy CLN1185, and the Nursing Documentation of Patient Care Policy CLN0647 by July 10, 2019.	Officer to develop recommendations for improvement. In collaboration with the Executive Director of Nursing Quality, Safety and Research and the Laboratory Medicine Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and Patient Blood Management Committee, the ECMS, and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Hospital will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate.	

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	Administration and Transfusion Reaction Policy CLN1115, which was published on May 19, 2019. Under the revised policy, nursing staff are to take the patient's vital signs prior to initiating the transfusion, 15 minutes into the transfusion, hourly from the start of the transfusion through completion of the transfusion, and at completion of the transfusion. They are required to assess the patient for signs and symptoms of transfusion reaction and document their observations hourly through completion of the transfusion, and at completion of the transfusion. The Electronic Health Record (EHR) includes a list of the symptoms of a transfusion reaction. If the nurse selects yes, the EHR generates a checklist of the symptoms allowing the nurse to select the symptoms that are present. blood component transfusion In addition, the Hospital's Nursing Documentation of Patient Care Policy CLN0647 was modified as follows: (i) to require nurses to document assessment and reassessment of the patient, prior to, during and after a procedure or treatment as indicated, within an appropriate time frame after the intervention for an evaluation of effectiveness and patient's response to the intervention, and appropriate follow up with the Credentialed Provider; and (ii) to require clear documentation for nursing work flow in the EHR, to include documentation of vital signs and suspected transfusion reaction in	RNs on leave who transfuse blood components must complete training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the enhanced nursing standards for administering and monitoring blood component transfusions, the Stop the Line for Patient Safety Policy CLN1185, and Nursing Documentation of Patient Care Policy CLN0647is included in the on-boarding process for new RNs who transfuse blood components.		

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	accordance with the Hospital's Blood Component Administration and Transfusion Reaction Policy LN1115. To ensure RNs document and detect infusion reactions: (1) Based on the National Patient Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol, published April 2018 by the Centers for Disease Control the Blood Component Administration and Transfusion Reaction Policy CLN1115 will be amended to include the definitions of hypotension and fever, by July 10, 2019. ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, which supports CLN1115, will be revised to address the hypotension and fever parameters by July 10, 2019. (2) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone to stop the line for an incomplete, conflicting or unclear order or in the event of a suspected transfusion reaction. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS approved the updated Stop the Line for Patient Safety Policy CLN1185, which was approved on June 20, 2019. Further training was developed on the modifications to the Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185.			

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	The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20, 2019. Following a 2-4 week prospective pilot in 3 areas where transfusions are administered (Phase 2), the Hemovigilance Unit will track the vital signs of each patient receiving transfusion services in real time (Phase 3). These vital signs will be reviewed by an RN under the supervision of an APP or physician 24/7 to complement the monitoring being provided at the bedside. The real time monitoring will also weight the vital signs and assign a risk number for each patient that is updated in real time, highlighting patients exhibiting potential signs of a reaction. Signs of a reaction will be referred to a member of the transfusion medicine practice. In addition to the monitoring being done by nursing under this POC, the Hemovigilance Unit will also review potential false negatives on an ongoing basis and report to the Transfusion and Patient Blood Management Committee. We are not formally submitting Phase 2 and 3 as part of our corrective action as these require a significant time investment			

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	to operationalize it across the hospital but we wanted CMS to be aware of its development as proof of our commitment to being an industry leader in developing new, innovative approaches to delivering the highest level of care.			
A 385(A)(3)	Hospital ensures that nurses notify the Credentialed Providers of changes in vital signs and condition of patients receiving transfusions of blood components as required under the Hospital policy. A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including the CMS/CLIA Steering Committee, members of the Transfusion and Patient Blood Management Committee, the Multidisciplinary Clinical Policies and Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and Transfusion Reaction Policy CLN1115. As part of this review over 6,000 patient charts who received blood transfusions were reviewed. A training program was developed by an inter-disciplinary team, including a transfusion medicine faculty member. This team was led by the Executive Director of Nursing, Professional Practice, Strategy and Execution and the Chief Education and Training Officer to develop curriculum and implement training for Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions and registered nurses (RN) who administer blood components	The Associate Director of G9 (Pediatrics) implemented immediate individualized one on one training for the two Pediatric RNs who cared for Patient #34 as follows: Nurse-Day Shift: Trained 12/7/18 and 12/31/18. Training included: • Coached on the escalation of concerns • Coached on appropriate documentation of escalation of concerns/provider notification • Nursing practice when carrying out the plan of care; prioritizing interventions Reviewed gaps in documentation related to hand-off documentation when the patient leaves the unit Nurse- Night Shift- Trained 12/20/18. Training included: • Gaps in vital sign monitoring and documentation for blood component administration • Reviewed signs and symptoms of reactions • Coached on appropriate documentation of escalation of concerns/provider notification • Reviewed institutional policy (CLN1115). RNs who administer blood components received educational information delivered in person by unit nursing leadership (Associate Directors, Nurse Managers, or Clinical Nurse Leaders) starting May 16, 2019 and completed by May 24, 2019. The topics addressed included adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, as supported by ATT1722, Guidelines for	A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by the OPI to determine adherence to (1) Blood Component Administration and Transfusion Reaction Policy CLN1115, including reporting to and consulting with the Credentialed Provider and the Transfusion Medicine Physician for suspected transfusion reactions, and (2) Stop the Line for Patient Safety Policy CLN1185, to stop the line in the event of a suspected transfusion reaction or an incomplete, conflicting or unclear order. OPI reviews the data with the Executive Director of Nursing Quality, Safety and Research, and the Laboratory Medicine Quality and Safety Officer to develop recommendations for improvement. In collaboration with the Executive Director of Nursing Quality, Safety and Research and the Laboratory Medicine Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and Patient Blood Management Committee, the ECMS, and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be	Chief Nursing Officer Completion Date: July 10, 2019

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	pursuant to the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes enhanced nursing standards for administering and monitoring blood components. The hospital nurse training "Blood Component Administration Competency" has been updated to include the following transfusion reaction symptoms: dry, flushed skin, pain in the abdomen and extremities, vomiting and bloody diarrhea. The training also addresses signs and symptoms of transfusion associated circulatory overload. Completed May 17, 2019. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was published on May 19, 2019. Under the revised policy, nursing staff are to take the patient's vital signs prior to initiating the transfusion, 15 minutes into the transfusion, hourly from the start of the transfusion through completion of the transfusion, and at completion of the transfusion. They are required to assess the patient for signs and symptoms of transfusion reaction and document their observations hourly through completion of the transfusion and at completion of the transfusion. The Electronic Health Record (EHR) includes a list of the symptoms of a transfusion reaction. If the nurse selects yes, the EHR generates a checklist of the	Identifying and Reporting a Transfusion Reaction, acceptable nursing standards for assessment, recognition, responding, and reporting symptoms of suspected transfusion reactions. RNs who administer blood components completed mandatory computer based training with knowledge assessment starting May 17, 2019 to be completed by July 10, 2019. The topics addressed within the computer based training on the Blood Component Administration and Transfusion Reaction Policy CLN1115, included increased monitoring of vital sign and patient assessment, recognizing, responding and reporting transfusion reactions to and consulting with the Credentialed Provider and the Transfusion Medicine Physician, and clarifying physician orders. Material was also reviewed regarding delivering patient education for participation in their care while receiving blood components. Additional training will be conducted regarding the changes to the Blood Component Administration and Transfusion Reaction Policy CLN1115 (including definitions of hypotension and fever, reporting suspected transfusion reactions to and consulting with the Credentialed Provider and the Transfusion Medicine Physician), and the Stop the Line for Patient Safety Policy CLN1185, by July 10, 2019. RNs on leave who transfuse blood components must complete training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the enhanced nursing standards for administering and monitoring blood component transfusions, Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new RNs who transfuse blood components. Credentialed Providers who obtain informed consent	adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Hospital will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate. Any Credentialed Provider deficiencies will be addressed through pertinent education and training, re-education and/or referral for confidential peer review through the medical staff.	

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	symptoms allowing the nurse to select the symptoms that are present. To ensure RNs notify the Credentialed Providers of condition of patients receiving transfusions of blood components as required under the Hospital policy: (1) Based on the National Patient Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol, published April 2018 by the Centers for Disease Control the Blood Component Administration and Transfusion Reaction Policy CLN1115 will be amended to include the definitions of hypotension and fever, by July 10, 2019. ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, which supports CLN1115, will be revised to address the hypotension and fever parameters by July 10, 2019. (2) The Blood Component Administration and Transfusion Reaction Policy CLN1115 was further modified to require that the Transfusion Medicine Physician is consulted regarding suspected blood component transfusion reactions. (3) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone to stop the line for an incomplete, conflicting or unclear order or in the event of a suspected transfusion reaction. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS approved the updated Stop the Line for Patient Safety Policy CLN1185, which was	for, order, administer or manage complications of blood component transfusions will complete the computer based training as outlined above by July 10, 2019. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood components and are on leave must complete the computer based training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 is included in the on-boarding process for new Credentialed Providers.		

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	approved on June 20, 2019. Further training was developed on the modifications to the Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185. The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20, 2019. The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20, 2019. Following a 2-4 week prospective pilot in 3 areas where transfusions are administered (Phase 2), the Hemovigilance Unit will track the vital signs of each patient receiving transfusion services in real time			

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	(Phase 3). These vital signs will be reviewed by an RN under the supervision of an APP or physician 24/7 to complement the monitoring being provided at the bedside. The real time monitoring will also weight the vital signs and assign a risk number for each patient that is updated in real time, highlighting patients exhibiting potential signs of a reaction. Signs of a reaction will be referred to a member of the transfusion medicine practice. In addition to the monitoring being done by nursing under this POC, the Hemovigilance Unit will also review potential false negatives on an ongoing basis and report to the Transfusion and Patient Blood Management Committee. We are not formally submitting Phase 2 and 3 as part of our corrective action as these require a significant time investment to operationalize it across the hospital but we wanted CMS to be aware of its development as proof of our commitment to being an industry leader in developing new, innovative approaches to delivering the highest level of care. This plan of correction is also addressed under the Plans of Correction Tags A 043, A 144, A 115, and A 409.			
A 385(A)(4)	The Hospital ensures that nurses have complete and accurate orders prior to initiating transfusions. Blood components are infused at the duration specified in the Credentialed Provider orders for transfusion. Orders are clarified as needed, and Credentialed Providers are notified if the orders are not followed.	All RNs who administer blood components received pertinent education and training with knowledge assessment to be completed by July 10, 2019. The topics addressed during the training included changes to the EHR Blood Component Order Sets, adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, Patient Care Orders Policy CLN1140, and Stop the Line for Patient Safety Policy CLN1185, obtaining complete and accurate	A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by the OPI to determine adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, EHR Credentialed Provider Order Sets, and Stop The Line DCLN1185, specifically that orders specify the duration for the	Chief Nursing Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including the CMS/CLIA Steering Committee, members of the Transfusion and Patient Blood Management Committee, the Multidisciplinary Clinical Policies and Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and Transfusion Reaction Policy CLN1115. As part of this review over 6,000 patient charts who received blood transfusions were reviewed. The Hospital took the following actions to ensure that RNs infuse blood components at the duration specified in the order, that orders are clarified as needed, and that Credentialed Providers are notified if the orders are not followed: (1) The Blood Component Administration and Transfusion Reaction Policy CLN1115 was further modified to require that blood components are administered via volumetric pump to ensure the duration of the transfusion is in accordance with the Credentialed Provider's orders. (Accordingly, blood components will not be administered via "gravity" flow). The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was approved on June 20, 2019. (2) To ensure clarity of Credentialed Provider orders, the Hospital's Patient Care	Credentialed Provider orders prior to initiating transfusions, infusing blood components at the duration specified in the Credentialed Provider order for transfusion, clarifying orders as necessary, notifying the Credentialed Provider if orders are not followed, and procedures for stopping the line for patient safety. July 10, 2019. Any RN on leave who transfuses blood components must complete the training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115, Patient Care Orders Policy CLN1140, and Stop the Line for Patient Safety Policy CLN1185, obtaining complete and accurate Credentialed Provider orders prior to initiating transfusions, infusing blood components at the duration specified in the Credentialed Provider order for transfusion, clarifying orders as necessary, notifying the Credentialed Provider if orders are not followed, and procedures for stopping the line for patient safety is included in the on-boarding process for new RNs who transfuse blood components.	transfusion, and the actual duration of the transfusion. OPI reviews the data with the Executive Director of Nursing Quality, Safety and Research, and the Laboratory Medicine Quality and Safety Officer to develop recommendations for improvement. In collaboration with the Executive Director of Nursing Quality, Safety and Research and the Laboratory Medicine Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and Patient Blood Management Committee, the ECMS, and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Executive Director of Nursing, Strategy, Practice and Execution and Executive Director of Quality, Safety and Research will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate.	

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	Orders Policy CLN1140 was modified as follows: (i) to require health care providers to seek clarification of incomplete, conflicting or unclear orders. The Executive Owner of the Patient Care Orders Policy CLN1140 (the Chief Medical Officer) and the ECMS, approved the updated Patient Care Orders Policy CLN1140, which was published on June 20, 2019. (3) Electronic Health Record (EHR) Credentialed Provider Order Set was modified to require duration of blood component transfusion. A Credentialed Provider must specify the duration of the blood component transfusion in order to complete the blood component order (hard stop). This change will be effective by July 10, 2019. (4) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone to stop the line for an incomplete, conflicting or unclear order or in the event of a suspected transfusion reaction. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Stop the Line for Patient Safety Policy CLN1185, which was approved on June 20, 2019. Training was developed by the Executive Director of Nursing, Professional Practice, Strategy and Execution to develop curriculum and implement training for registered nurses (RN) who administer blood components pursuant to the Blood Component Administration and			

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	Transfusion Reaction Policy CLN1115, the Stop The Line for Patient Safety Policy CLN 1185, the Patient Care Orders Policy CLN 1140, and the EHR Order Set. This plan of correction is also addressed under Plan of Correction Tag A 409(D).			
A 385(A)(5)	The Hospital ensures that nurses follow Credentialed Provider orders for transfusion rates (duration) for patients. A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including the CMS/CLIA Steering Committee, members of the Transfusion and Patient Blood Management Committee, the Multidisciplinary Clinical Policies and Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and Transfusion Reaction Policy CLN1115. As part of this review over 6,000 patient charts who received blood transfusions were reviewed. The Hospital took the following actions to ensure complete and accurate orders for blood components, that RNs infuse blood components at the duration specified in the order, that orders are clarified as needed, and that Credentialed Providers are notified if the orders are not followed: (1) The Blood Component Administration and Transfusion Reaction Policy CLN1115 was further modified to require that blood components are administered via volumetric pump to ensure the duration of the transfusion is in accordance with	All RNs who administer blood components received pertinent education and training with knowledge assessment to be completed by July 10, 2019. The topics addressed during the training included changes to the EHR Blood Component Order Sets, adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, Patient Care Orders Policy CLN1140, and Stop the Line for Patient Safety Policy CLN1185, obtaining complete and accurate Credentialed Provider orders prior to initiating transfusions, infusing blood components at the duration specified in the Credentialed Provider order for transfusion, clarifying orders as necessary, notifying the Credentialed Provider if orders are not followed, and procedures for stopping the line for patient safety. July 10, 2019. Any RN on leave who transfuses blood components must complete the training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115, Patient Care Orders Policy CLN1140, and Stop the Line for Patient Safety Policy CLN1185, obtaining complete and accurate Credentialed Provider orders prior to initiating transfusions, infusing blood components at the duration specified in the Credentialed Provider order for transfusion, clarifying orders as necessary, notifying the Credentialed Provider if orders are not followed, and procedures for stopping the line for patient safety is included in the on-boarding process for new RNs who transfuse blood components.	A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by the OPI to determine adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, EHR Credentialed Provider Order Sets, and Stop The Line DCLN1185, specifically that orders specify the duration for the transfusion, and the actual duration of the transfusion. OPI reviews the data with the Executive Director of Nursing Quality, Safety and Research, and the Laboratory Medicine Quality and Safety Officer to develop recommendations for improvement. In collaboration with the Executive Director of Nursing Quality, Safety and Research and the Laboratory Medicine Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and Patient Blood Management Committee, the ECMS, and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee	Chief Nursing Officer Completion Date: July 10, 2019

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	the Credentialed Provider's orders. (Accordingly, blood components will not be administered via "gravity" flow). The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was approved on June 20, 2019. (2) To ensure clarity of Credentialed Provider orders, the Hospital's Patient Care Orders Policy CLN1140 was modified as follows: (i) to require health care providers to seek clarification of incomplete, conflicting or unclear orders. The Executive Owner of the Patient Care Orders Policy CLN1140 (the Chief Medical Officer) and the ECMS, approved the updated Patient Care Orders Policy CLN1140, which was published on June 20, 2019. (3) Electronic Health Record (EHR) Credentialed Provider Order Set was modified to require duration of blood component transfusion. A Credentialed Provider must specify the duration of the blood component transfusion in order to complete the blood component order (hard stop). This change will be effective by July 10, 2019. (4) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone to stop the line for an incomplete, conflicting or unclear order or in the event of a suspected transfusion reaction.		and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Executive Director of Nursing, Strategy, Practice and Execution and Executive Director of Quality, Safety and Research will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate.	

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Stop the Line for Patient Safety Policy CLN1185, which was approved on June 20, 2019. Training was developed by the Executive Director of Nursing, Professional Practice, Strategy and Execution to develop curriculum and implement training for registered nurses (RN) who administer blood components pursuant to the Blood Component Administration and Transfusion Reaction Policy CLN1115, the Stop The Line for Patient Safety Policy CLN 1185, the Patient Care Orders Policy CLN 1140, and the EHR Order Set. This plan of correction is also addressed under Plan of Correction Tag A 409(E).			
A 385(B)	The Chief Nursing Officer reviewed Hospital's inpatient nurse staffing grid, and hospital-wide inpatient staffing, including on G9 Pediatrics SW&NE and G9 Pediatric Intensive Care Services NW to ensure adequate staffing. The Nurse Staffing Advisory Committee reviewed hospital-wide inpatient nurse staffing grid. June 20, 2019. This plan of correction is also addressed under Plan of Correction Tag A 392.	Nurse Staffing Policy and Plan, CLN1054 requires adequate (i.e., minimum) numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. This Policy was reviewed by the Chief Nursing Officer and the Nurse Staffing Advisory Committee, but no substantive changes were needed. A new staffing matrix was created to reflect minimum staffing in accordance with Nurse Staffing Policy and Plan, CLN1054. The staffing matrix was approved by the Chief of Nursing and the Nurse Staffing Advisory Committee on June 20, 2019.	The Chief Nursing Officer approved a new staffing matrix format to ensure adequate staffing for hospital-wide inpatient units on June 20, 2019. The new matrix was reviewed with the Nurse Staffing Advisory Committee on June 20, 2019. The Division Administrator for Nursing will educate clinical leaders for all inpatient units on the use and implementation of the new staffing matrix, by July 10, 2019 Any nurse leader on leave will be educated on the new staffing matrix upon return to work. The Division Administrator for Nursing will review the staffing levels against the	Chief Nursing Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
			staffing matrix monthly for the first two months, and at least twice each year thereafter. The biannual assessment will be provided to the Nurse Staffing Advisory Committee and the Governing Body.	
A 385(C)	The Chief Nursing Officer and the Executive Director of Nursing, Professional Practice, Strategy and Execution reviewed the Hospital's Nursing Staff Competency Policy CLN0670 and the status of current competencies in clinical areas. The Hospital's Nursing Staff Competency Policy CLN0670 was revised to enhance the annual assessment and validation of the competence of nursing staff, and to include effective monitoring of annual competence assessment of nursing staff. Changes to the Nursing Staff Competency Policy CLN0670 were reviewed with the Competency Steering Committee and feedback was solicited on June 14, 2019. The Chief Nursing Officer, and the Executive Director of Nursing, Practice, Strategy and Execution approved the updated Nursing Staff Competency Policy CLN0670 on June 18, 2019. This plan of correction is also addressed under Plan of Correction Tag A 397.	The Executive Director of Nursing, Professional Practice, Strategy and Execution will develop training on the Hospital's Nursing Staff Competency Policy CLN0670 for all clinical nursing personnel. The topics addressed during the training will include: • Overview of policy changes • Annual needs assessment • Role of competency steering committee • Manager and Employee responsibilities Training will be completed by July 10, 2019. A competency matrix will be used to identify expected competencies by area and role of nursing staff to provide clarity regarding expected annual and unit/area-specific competencies for clinical nursing staff. An annual competency validation summary will be developed as a single source of competencies and required educational activities for individual staff members. The document will reside in the employee personnel record. The Executive Director of Nursing, Professional Practice, Strategy and Execution in collaboration with the Unit leadership, reviewed the personnel files of	The Executive Director of Nursing, Professional Practice, Strategy and Execution, in conjunction with the Director of Nursing Education and the Competency Steering Committee will develop a process to monitor compliance with the Hospital's Nursing Staff Competency Policy CLN0670, which includes • Annually perform review of the annual needs assessment for each area • Oversight of all competency content to ensure adherence to evidence-based standards • Standardization of forms and reporting processes • Annual review of educational evaluations to ensure content meets needs of identified learners • Quarterly review of nursing quality metrics to identify areas where competencies or further education are needed. • Quarterly review of new processes or procedures to identify areas where competencies or further education are needed.	Chief Nursing Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
		Staff #1, Staff #47, and Staff #43, and ensured that each of these staff members had an annual competency validation before caring for patients in accordance with the patients' needs by July 10, 2019. The revised process will be introduced to nursing leaders (Directors of Nursing, Associate Directors, Nurse Managers, Clinical Nurse Leaders, and educators) by July 10, 2019. Compliance is reinforced regularly by nursing leadership. Any clinical nursing personnel on leave (FMLA or vacation) must complete the training before returning to work.	The revised process will be completed by July 10, 2019. The updated process will also be initiated by July 10, 2019. Any nurse not in compliance with the Hospital's Nursing Staff Competency Policy CLN0670, will be removed from providing patient care until annual competencies are completed.	
Tag A 392 Staffing and Delivery of Care	Hospital nursing service has adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. Hospital has supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.			
A 392	The Chief Nursing Officer reviewed Hospital's inpatient nurse staffing grid, and hospital-wide inpatient staffing, including on G9 Pediatrics SW&NE and G9 Pediatric Intensive Care Services NW to ensure adequate staffing. The Nurse Staffing Advisory Committee reviewed hospital-wide inpatient nurse staffing grid. June 20, 2019. This plan of correction is also addressed under Plan of Correction Tag A 385.	Nurse Staffing Policy and Plan, CLN1054 requires adequate (i.e., minimum) numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. This Policy was reviewed by the Chief Nursing Officer and the Nurse Staffing Advisory Committee, but no substantive changes were needed. A new staffing matrix was created to reflect minimum staffing in accordance with Nurse Staffing Policy and Plan, CLN1054. The staffing matrix was approved by the Chief of Nursing and the Nurse Staffing Advisory Committee on June 20, 2019.	The Chief Nursing Officer approved a new staffing matrix format to ensure adequate staffing for hospital-wide inpatient units on June 20, 2019. The new matrix was reviewed with the Nurse Staffing Advisory Committee on June 20, 2019. The Division Administrator for Nursing will educate clinical leaders for all inpatient units on the use and implementation of the new staffing matrix, by July 10, 2019 Any nurse leader on leave will be educated on the new staffing matrix upon return to work. The Division Administrator for Nursing	Chief Nursing Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
			will review the staffing levels against the staffing matrix monthly for the first two months, and at least twice each year thereafter. The biannual assessment will be provided to the Nurse Staffing Advisory Committee and the Governing Body.	
Tag A 397 Patient Care Assignments	Hospital ensures a registered nurse assigns the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.			
A 397	The Chief Nursing Officer and the Executive Director of Nursing, Professional Practice, Strategy and Execution reviewed the Hospital's Nursing Staff Competency Policy CLN0670 and the status of current competencies in clinical areas. The Hospital's Nursing Staff Competency Policy CLN0670 was revised to enhance the annual assessment and validation of the competence of nursing staff, and to include effective monitoring of annual competence assessment of nursing staff. Changes to the Nursing Staff Competency Policy CLN0670 were reviewed with the Competency Steering Committee and feedback was solicited on June 14, 2019. The Chief Nursing Officer, and the Executive Director of Nursing, Practice, Strategy and Execution approved the updated Nursing Staff Competency Policy	The Executive Director of Nursing, Professional Practice, Strategy and Execution will develop training on the Hospital's Nursing Staff Competency Policy CLN0670 for all clinical nursing personnel. The topics addressed during the training will include: • Overview of policy changes • Annual needs assessment • Role of competency steering committee • Manager and Employee responsibilities Training will be completed by July 10, 2019. A competency matrix will be used to identify expected competencies by area and role of nursing staff to provide clarity regarding expected annual and unit/area-specific competencies for clinical nursing staff. An annual competency validation summary will be developed as a single source of competencies and required educational activities for individual staff	The Executive Director of Nursing, Professional Practice, Strategy and Execution, in conjunction with the Director of Nursing Education and the Competency Steering Committee will develop a process to monitor compliance with the Hospital's Nursing Staff Competency Policy CLN0670, which includes • Annually perform review of the annual needs assessment for each area • Oversight of all competency content to ensure adherence to evidence-based standards • Standardization of forms and reporting processes • Annual review of educational evaluations to ensure content meets needs of identified learners • Quarterly review of nursing quality metrics to identify areas	Chief Nursing Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	CLN0670 on June 18, 2019. This plan of correction is also addressed under Plan of Correction Tag A 385.	members. The document will reside in the employee personnel record. The Executive Director of Nursing, Professional Practice, Strategy and Execution in collaboration with the Unit leadership, reviewed the personnel files of Staff #1, Staff #47, and Staff #43, and ensured that each of these staff members had an annual competency validation before caring for patients in accordance with the patients' needs by July 10, 2019. The revised process will be introduced to nursing leaders (Directors of Nursing, Associate Directors, Nurse Managers, Clinical Nurse Leaders, and educators) by July 10, 2019. Compliance is reinforced regularly by nursing leadership. Any clinical nursing personnel on leave (FMLA or vacation) must complete the training before returning to work.	where competencies or further education are needed. • Quarterly review of new processes or procedures to identify areas where competencies or further education are needed. The revised process will be completed by July 10, 2019. The updated process will also be initiated by July 10, 2019. Any nurse not in compliance with the Hospital's Nursing Staff Competency Policy CLN0670, will be removed from providing patient care until annual competencies are completed.	
Tag A 409 Blood Transfusions and IV Medications	Hospital ensures blood component transfusions and intravenous medications are administered in accordance with State law and approved medical staff policies and procedures. If blood component transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, Hospital ensures the personnel have special training for this duty.			
A 409	Hospital ensures that blood component transfusions are administered in accordance with Hospital's policy/procedures and acceptable nursing standards. A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including the CMS/CLIA Steering Committee,	The Associate Director of G9 (Pediatrics) implemented immediate individualized one on one training for the two Pediatric RNs who cared for Patient #34 as follows: Nurse-Day Shift: Trained 12/7/18 and 12/31/18. Training included: • Coached on the escalation of concerns • Coached on appropriate documentation of escalation of concerns/provider notification	A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by the OPI to determine adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115 for vital signs and monitoring, that orders specify the duration for the transfusion, and the actual duration of the transfusion. OPI reviews the data with the	Chief Operating Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	members of the Transfusion and Patient Blood Management Committee, the Multidisciplinary Clinical Policies and Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and Transfusion Reaction Policy CLN1115. As part of this review over 6,000 patient charts who received blood transfusions were reviewed. A training program was developed by an inter-disciplinary team, including a transfusion medicine faculty member. This team was led by the Executive Director of Nursing, Professional Practice, Strategy and Execution and the Chief Education and Training Officer to develop curriculum and implement training for Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions and registered nurses (RN) who administer blood components pursuant to the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes enhanced nursing standards for administering and monitoring blood components. The hospital nurse training "Blood Component Administration Competency" has been updated to include the following transfusion reaction symptoms: dry, flushed skin, pain in the abdomen and extremities, vomiting and bloody diarrhea. The training also addresses signs and symptoms of transfusion associated circulatory overload. Completed May 17, 2019.	• Nursing practice when carrying out the plan of care; prioritizing interventions • Reviewed gaps in documentation related to hand-off documentation when the patient leaves the unit Nurse- Night Shift- Trained 12/20/18. Training included: • Gaps in vital sign monitoring and documentation for blood component administration • Reviewed signs and symptoms of reactions • Coached on appropriate documentation of escalation of concerns/provider notification • Reviewed institutional policy (CLN1115). RNs who administer blood components received educational information delivered in person by unit nursing leadership (Associate Directors, Nurse Managers, or Clinical Nurse Leaders) starting May 16, 2019 and completed by May 24, 2019. The topics addressed included adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, as supported by ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, acceptable nursing standards for assessment, recognition, responding, and reporting symptoms of suspected transfusion reactions. RNs who administer blood components completed mandatory computer based training with knowledge assessment starting May 17, 2019 to be completed by July 10, 2019. The topics addressed within the computer based training on the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes increased monitoring of vital sign and patient assessment, recognizing, responding and reporting transfusion reactions. Material was also reviewed regarding delivering patient education for participation in their care while	Executive Director of Nursing Quality, Safety and Research, and the Laboratory Medicine Quality and Safety Officer to develop recommendations for improvement. In collaboration with the Executive Director of Nursing Quality, Safety and Research and the Laboratory Medicine Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and Patient Blood Management Committee, the ECMS, and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Hospital will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate.	

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was published on May 19, 2019. Under the revised policy, nursing staff are to take the patient's vital signs prior to initiating the transfusion, 15 minutes into the transfusion, hourly from the start of the transfusion through completion of the transfusion, and at completion of the transfusion. They are required to assess the patient for signs and symptoms of transfusion reaction and document their observations hourly through completion of the transfusion, and at completion of the transfusion. The Electronic Health Record (EHR) includes a list of the symptoms of a transfusion reaction. If the nurse selects yes, the EHR generates a checklist of the symptoms allowing the nurse to select the symptoms that are present. To ensure RNs administer blood components in accordance with Hospital policy and acceptable nursing standards: (1) The Blood Component Administration and Transfusion Reaction Policy CLN1115 was further modified to require that blood components are administered via volumetric pump to ensure the duration of the transfusion is in accordance with the physician's orders. (Accordingly, blood components will not be administered via "gravity" flow).	receiving blood components. Additional training will be conducted regarding the changes to the EHR Blood Component Order Sets, the modifications to the Blood Component Administration and Transfusion Reaction Policy CLN1115 (including the use of volumetric pumps, orders to include the duration of the transfusion, and definitions of hypotension and fever, as described in ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction), and the Stop the Line for Patient Safety Policy CLN1185, by July 10, 2019. RNs on leave who transfuse blood components must complete training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the enhanced nursing standards for administering and monitoring blood component transfusions, and the Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new RNs who transfuse blood components. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions will complete the computer based training as outlined above by July 10, 2019. Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood components and are on leave must complete the computer based training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new Credentialed Providers.		

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was approved on June 20, 2019. (2) Based on the National Patient Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol, published April 2018 by the Centers for Disease Control the Blood Component Administration and Transfusion Reaction Policy CLN1115 will be amended to include the definitions of hypotension and fever, by July 10, 2019. ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, which supports CLN1115, will be revised to address the hypotension and fever parameters by July 10, 2019. (3) EHR Physician Blood Component Order Set was modified to require duration of blood component transfusion. A Credentialed Provider must specify the duration of the blood component transfusion in order to complete the blood component order (hard stop). This change will be effective by July 10, 2019. (4) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone to stop the line for an incomplete, conflicting or unclear order or in the event of a suspected transfusion reaction. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS approved the updated Stop the Line for	A reminder communication will be sent to all nursing staff who administer and monitor transfusions regarding the process for reporting a suspected transfusion reaction, by July 10, 2019.		

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	Patient Safety Policy CLN1185, which was approved on June 20, 2019. Further training was developed on the EHR Blood Component Order Sets, and the modifications to the Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185. The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20, 2019. Following a 2-4 week prospective pilot in 3 areas where transfusions are administered (Phase 2), the Hemovigilance Unit will track the vital signs of each patient receiving transfusion services in real time (Phase 3). These vital signs will be reviewed by an RN under the supervision of an Advanced Practice Provider (APP) or physician 24/7 to complement the monitoring being provided at the bedside. The real time monitoring will also weight the vital signs and assign a risk number for each patient that is updated in real time, highlighting patients exhibiting potential signs of a reaction. Signs of a reaction will be referred to a member of the transfusion medicine practice. In addition to the			

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	monitoring being done by nursing under this POC, the Hemovigilance Unit will also review potential false negatives on an ongoing basis and report to the Transfusion and Patient Blood Management Committee. We are not formally submitting Phase 2 and 3 as part of our corrective action as these require a significant time investment to operationalize it across the hospital but we wanted CMS to be aware of its development as proof of our commitment to being an industry leader in developing new, innovative approaches to delivering the highest level of care. This plan of correction is also addressed under Plans of Correction Tags A 043, A 144, A 385, and A 115.			
A 409(A)	The Hospital ensures that nurses continually assess patients during transfusion of blood components. A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including the CMS/CLIA Steering Committee, members of the Transfusion and Patient Blood Management Committee, the Multidisciplinary Clinical Policies and Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and Transfusion Reaction Policy CLN1115. As part of this review over 6,000 patient charts who received blood transfusions were reviewed. A training program was developed by an	The Associate Director of G9 (Pediatrics) implemented immediate individualized one on one training for the two Pediatric RNs who cared for Patient #34 as follows: Nurse-Day Shift: Trained 12/7/18 and 12/31/18. Training included: • Coached on the escalation of concerns • Coached on appropriate documentation of escalation of concerns/provider notification • Nursing practice when carrying out the plan of care; prioritizing interventions • Reviewed gaps in documentation related to hand-off documentation when the patient leaves the unit RNs who administer blood components received educational information delivered in person by unit nursing leadership (Associate Directors, Nurse Managers, or Clinical Nurse Leaders) starting May 16,	A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by the OPI to determine adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115 for the for vital signs and monitoring. OPI reviews the data with the Executive Director of Nursing Quality, Safety and Research, and the Laboratory Medicine Quality and Safety Officer to develop recommendations for improvement. In collaboration with the Executive Director of Nursing Quality, Safety and Research and the Laboratory Medicine Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and Patient Blood Management Committee, the ECMS, and the QAPI Council monthly	Chief Operating Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	inter-disciplinary team, including a transfusion medicine faculty member. This team was led by the Executive Director of Nursing, Professional Practice, Strategy and Execution and the Chief Education and Training Officer to develop curriculum and implement training for Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions and registered nurses (RN) who administer blood components pursuant to the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes enhanced nursing standards for administering and monitoring blood components. The hospital nurse training "Blood Component Administration Competency" has been updated to include the following transfusion reaction symptoms: dry, flushed skin, pain in the abdomen and extremities, vomiting and bloody diarrhea. The training also addresses signs and symptoms of transfusion associated circulatory overload. Completed May 17, 2019. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was published on May 19, 2019. Under the revised policy, nursing staff are to take the patient's vital signs prior to initiating the transfusion, 15 minutes into the transfusion, hourly from the start of the transfusion through completion of the	2019 and completed by May 24, 2019. The topics addressed included adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, as supported by ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, acceptable nursing standards for continual assessment, recognition, responding, and reporting symptoms of suspected transfusion reactions. RNs who administer blood components completed mandatory computer based training with knowledge assessment starting May 17, 2019 to be completed by July 10, 2019. The topics addressed within the computer based training on the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes increased monitoring of vital sign and patient assessment, recognizing, responding and reporting transfusion reactions. Material was also reviewed regarding delivering patient education for participation in their care while receiving blood components. Additional training will be conducted regarding the changes to the Blood Component Administration and Transfusion Reaction Policy CLN1115 (including definitions of hypotension and fever, as described in ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction), and the Stop the Line for Patient Safety Policy CLN1185, by July 10, 2019. RNs on leave who transfuse blood components must complete training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the enhanced nursing standards for administering and monitoring blood component transfusions, and the Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new RNs who transfuse blood components.	for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Hospital will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate.	

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	transfusion, and at completion of the transfusion. They are required to assess the patient for signs and symptoms of transfusion reaction and document their observations hourly through completion of the transfusion, and at completion of the transfusion. The Electronic Health Record (EHR) includes a list of the symptoms of a transfusion reaction. If the nurse selects yes, the EHR generates a checklist of the symptoms allowing the nurse to select the symptoms that are present. To ensure RNs administer blood components in accordance with Hospital policy and acceptable nursing standards: (1) Based on the National Patient Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol, published April 2018 by the Centers for Disease Control the Blood Component Administration and Transfusion Reaction Policy CLN1115 will be amended to include the definitions of hypotension and fever, by July 10, 2019. ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, which supports CLN1115, will be revised to address the hypotension and fever parameters by July 10, 2019. (2) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone to stop the line for an incomplete, conflicting or unclear order or in the event of a suspected transfusion reaction.			

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS approved the updated Stop the Line for Patient Safety Policy CLN1185, which was approved on June 20, 2019. Further training was developed on the modifications to the Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185. The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20, 2019. Following a 2-4 week prospective pilot in 3 areas where transfusions are administered (Phase 2), the Hemovigilance Unit will track the vital signs of each patient receiving transfusion services in real time (Phase 3). These vital signs will be reviewed by an RN under the supervision of an APP or physician 24/7 to complement the monitoring being provided at the bedside. The real time monitoring will also weight the vital signs and assign a risk number for each patient that is updated in real time, highlighting patients exhibiting potential signs of a			

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	reaction. Signs of a reaction will be referred to a member of the transfusion medicine practice. In addition to the monitoring being done by nursing under this POC, the Hemovigilance Unit will also review potential false negatives on an ongoing basis and report to the Transfusion and Patient Blood Management Committee. We are not formally submitting Phase 2 and 3 as part of our corrective action as these require a significant time investment to operationalize it across the hospital but we wanted CMS to be aware of its development as proof of our commitment to being an industry leader in developing new, innovative approaches to delivering the highest level of care. This plan of correction is also addressed under the Plans of Correction Tags A 043, A 144, A 385, and A 115.			
A 409(B)	The Hospital ensures that RNs provide and documented timely, complete and accurate assessments on patients who experienced transfusion reactions. A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including the CMS/CLIA Steering Committee, members of the Transfusion and Patient Blood Management Committee, the Multidisciplinary Clinical Policies and Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and Transfusion Reaction Policy CLN1115. As part of this review over 6,000 patient charts who received blood transfusions	RNs who administer blood components received educational information delivered in person by unit nursing leadership (Associate Directors, Nurse Managers, or Clinical Nurse Leaders) starting May 16, 2019 and completed by May 24, 2019. The topics addressed included adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, as supported by ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, acceptable nursing standards for continual assessment, recognition, responding, and reporting symptoms of suspected transfusion reactions. RNs who administer blood components completed mandatory computer based training with knowledge assessment starting May 17, 2019 to be completed by July 10, 2019. The topics addressed within the computer based training on the Blood Component	A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by the OPI to determine adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115 for the for vital signs and monitoring and documentation in accordance with Nursing Documentation of Patient Care Policy CLN0647. OPI reviews the data with the Executive Director of Nursing Quality, Safety and Research, and the Laboratory Medicine Quality and Safety Officer to develop recommendations for improvement. In collaboration with the Executive Director of Nursing Quality, Safety and	Chief Operating Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	were reviewed. A training program was developed by an inter-disciplinary team, including a transfusion medicine faculty member. This team was led by the Executive Director of Nursing, Professional Practice, Strategy and Execution and the Chief Education and Training Officer to develop curriculum and implement training for Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions and registered nurses (RN) who administer blood components pursuant to the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes enhanced nursing standards for administering and monitoring blood components. The hospital nurse training "Blood Component Administration Competency" has been updated to include the following transfusion reaction symptoms: dry, flushed skin, pain in the abdomen and extremities, vomiting and bloody diarrhea. The training also addresses signs and symptoms of transfusion associated circulatory overload. Completed May 17, 2019. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was published on May 19, 2019. Under the revised policy, nursing staff are to take the patient's vital signs prior to	Administration and Transfusion Reaction Policy CLN1115, which includes increased monitoring of vital sign and patient assessment, recognizing, responding and reporting transfusion reactions. Material was also reviewed regarding delivering patient education for participation in their care while receiving blood components. Additional training will be conducted regarding the changes to the Blood Component Administration and Transfusion Reaction Policy CLN1115 (including definitions of hypotension and fever, as described in ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction), the Stop the Line for Patient Safety Policy CLN1185, and the Nursing Documentation of Patient Care Policy CLN0647 by July 10, 2019. RNs on leave who transfuse blood components must complete training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the enhanced nursing standards for administering and monitoring blood component transfusions, the Stop the Line for Patient Safety Policy CLN1185, and Nursing Documentation of Patient Care Policy CLN0647is included in the on-boarding process for new RNs who transfuse blood components.	Research and the Laboratory Medicine Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and Patient Blood Management Committee, the ECMS, and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Hospital will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate.	

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	initiating the transfusion, 15 minutes into the transfusion, hourly from the start of the transfusion through completion of the transfusion, and at completion of the transfusion. They are required to assess the patient for signs and symptoms of transfusion reaction and document their observations hourly through completion of the transfusion, and at completion of the transfusion. The Electronic Health Record (EHR) includes a list of the symptoms of a transfusion reaction. If the nurse selects yes, the EHR generates a checklist of the symptoms allowing the nurse to select the symptoms that are present. In addition, the Hospital's Nursing Documentation of Patient Care Policy CLN0647 was modified as follows: (i) to require nurses to document assessment and reassessment of the patient, prior to, during and after a procedure or treatment as indicated, within an appropriate time frame after the intervention for an evaluation of effectiveness and patient's response to the intervention, and appropriate follow up with the Credentialed Provider; and (ii) to require clear documentation for nursing work flow in the EHR, to include documentation of vital signs and suspected transfusion reaction in accordance with the Hospital's Blood Component Administration and Transfusion Reaction Policy LN1115. To ensure RNs document and detect infusion reactions: (1) Based on the National Patient Safety			

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	Network Biovigilance Component Hemovigilance Module Surveillance Protocol, published April 2018 by the Centers for Disease Control the Blood Component Administration and Transfusion Reaction Policy CLN1115 will be amended to include the definitions of hypotension and fever, by July 10, 2019. ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, which supports CLN1115, will be revised to address the hypotension and fever parameters by July 10, 2019. EPIC parameters will be modified, based on the above Network Biovigilance Component Hemovigilance Module Surveillance Protocol by July 10, 2019. (2) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone to stop the line for an incomplete, conflicting or unclear order or in the event of a suspected transfusion reaction. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS approved the updated Stop the Line for Patient Safety Policy CLN1185, which was approved on June 20, 2019. Further training was developed on the modifications to the Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185. The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion			

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20, 2019. Following a 2-4 week prospective pilot in 3 areas where transfusions are administered (Phase 2), the Hemovigilance Unit will track the vital signs of each patient receiving transfusion services in real time (Phase 3). These vital signs will be reviewed by an RN under the supervision of an APP or physician 24/7 to complement the monitoring being provided at the bedside. The real time monitoring will also weight the vital signs and assign a risk number for each patient that is updated in real time, highlighting patients exhibiting potential signs of a reaction. Signs of a reaction will be referred to a member of the transfusion medicine practice. In addition to the monitoring being done by nursing under this POC, the Hemovigilance Unit will also review potential false negatives on an ongoing basis and report to the Transfusion and Patient Blood Management Committee. We are not formally submitting Phase 2 and 3 as part of our corrective action as these require a significant time investment to operationalize it across the hospital but we wanted CMS to be aware of its development as proof of our commitment			

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	to being an industry leader in developing new, innovative approaches to delivering the highest level of care.			
A 409(C)	Hospital ensures that nurses notify the Credentialed Providers of changes in vital signs and condition of patients receiving transfusions of blood components as required under the Hospital policy. A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including the CMS/CLIA Steering Committee, members of the Transfusion and Patient Blood Management Committee, the Multidisciplinary Clinical Policies and Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and Transfusion Reaction Policy CLN1115. As part of this review over 6,000 patient charts who received blood transfusions were reviewed. A training program was developed by an inter-disciplinary team, including a transfusion medicine faculty member. This team was led by the Executive Director of Nursing, Professional Practice, Strategy and Execution and the Chief Education and Training Officer to develop curriculum and implement training for Credentialed Providers who obtain informed consent for, order, administer or manage complications of blood component transfusions and registered nurses (RN) who administer blood components pursuant to the Blood Component Administration and Transfusion Reaction Policy CLN1115, which includes enhanced	The Associate Director of G9 (Pediatrics) implemented immediate individualized one on one training for the two Pediatric RNs who cared for Patient #34 as follows: Nurse-Day Shift: Trained 12/7/18 and 12/31/18. Training included: • Coached on the escalation of concerns • Coached on appropriate documentation of escalation of concerns/provider notification • Nursing practice when carrying out the plan of care; prioritizing interventions Reviewed gaps in documentation related to hand-off documentation when the patient leaves the unit Nurse- Night Shift- Trained 12/20/18. Training included: • Gaps in vital sign monitoring and documentation for blood component administration • Reviewed signs and symptoms of reactions • Coached on appropriate documentation of escalation of concerns/provider notification • Reviewed institutional policy (CLN1115). RNs who administer blood components received educational information delivered in person by unit nursing leadership (Associate Directors, Nurse Managers, or Clinical Nurse Leaders) starting May 16, 2019 and completed by May 24, 2019. The topics addressed included adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, as supported by ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, acceptable nursing standards for assessment, recognition, responding, and reporting symptoms of	A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by the OPI to determine adherence to (1) Blood Component Administration and Transfusion Reaction Policy CLN1115, including reporting to and consulting with the Credentialed Provider and the Transfusion Medicine Physician for suspected transfusion reactions, and (2) Stop the Line for Patient Safety Policy CLN1185, to stop the line in the event of a suspected transfusion reaction or an incomplete, conflicting or unclear order. OPI reviews the data with the Executive Director of Nursing Quality, Safety and Research, and the Laboratory Medicine Quality and Safety Officer to develop recommendations for improvement. In collaboration with the Executive Director of Nursing Quality, Safety and Research and the Laboratory Medicine Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and Patient Blood Management Committee, the ECMS, and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee	Chief Operating Officer Completion Date: July 10, 2019

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	nursing standards for administering and monitoring blood components. The hospital nurse training "Blood Component Administration Competency" has been updated to include the following transfusion reaction symptoms: dry, flushed skin, pain in the abdomen and extremities, vomiting and bloody diarrhea. The training also addresses signs and symptoms of transfusion associated circulatory overload. Completed May 17, 2019. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was published on May 19, 2019. Under the revised policy, nursing staff are to take the patient's vital signs prior to initiating the transfusion, 15 minutes into the transfusion, hourly from the start of the transfusion through completion of the transfusion, and at completion of the transfusion. They are required to assess the patient for signs and symptoms of transfusion reaction and document their observations hourly through completion of the transfusion and at completion of the transfusion. The Electronic Health Record (EHR) includes a list of the symptoms of a transfusion reaction. If the nurse selects yes, the EHR generates a checklist of the symptoms allowing the nurse to select the symptoms that are present.	suspected transfusion reactions. RNs who administer blood components completed mandatory computer based training with knowledge assessment starting May 17, 2019 to be completed by July 10, 2019. The topics addressed within the computer based training on the Blood Component Administration and Transfusion Reaction Policy CLN1115, included increased monitoring of vital sign and patient assessment, recognizing, responding and reporting transfusion reactions to and consulting with the Credentialed Provider and the Transfusion Medicine Physician, and clarifying physician orders. Material was also reviewed regarding delivering patient education for participation in their care while receiving blood components. Additional training will be conducted regarding the changes to the Blood Component Administration and Transfusion Reaction Policy CLN1115 (including definitions of hypotension and fever, reporting suspected transfusion reactions to and consulting with the Credentialed Provider and the Transfusion Medicine Physician), and the Stop the Line for Patient Safety Policy CLN1185, by July 10, 2019. RNs on leave who transfuse blood components must complete training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115 and the enhanced nursing standards for administering and monitoring blood component transfusions, Stop the Line for Patient Safety Policy CLN1185 is included in the on-boarding process for new RNs who transfuse blood components.	and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Hospital will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate.	

Tag	Plan for correcting the cited deficiency	Procedure for implementing the acceptable plan of correction	Follow-up/Monitoring	Person Responsible Completion Date
	To ensure RNs notify the Credentialed Providers of condition of patients receiving transfusions of blood components as required under the Hospital policy: (1) Based on the National Patient Safety Network Biovigilance Component Hemovigilance Module Surveillance Protocol, published April 2018 by the Centers for Disease Control the Blood Component Administration and Transfusion Reaction Policy CLN1115 will be amended to include the definitions of hypotension and fever, by July 10, 2019. ATT1722, Guidelines for Identifying and Reporting a Transfusion Reaction, which supports CLN1115, will be revised to address the hypotension and fever parameters by July 10, 2019. (2) The Blood Component Administration and Transfusion Reaction Policy CLN1115 was further modified to require that the Transfusion Medicine Physician is consulted regarding suspected blood component transfusion reactions. (3) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone to stop the line for an incomplete, conflicting or unclear order or in the event of a suspected transfusion reaction. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS approved the updated Stop the Line for Patient Safety Policy CLN1185, which was approved on June 20, 2019. Further training was developed on the			

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	modifications to the Blood Component Administration and Transfusion Reaction Policy CLN1115 and the Stop the Line for Patient Safety Policy CLN1185. The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20, 2019. The hospital has developed a Hemovigilance Unit that will track the vital signs of each patient receiving transfusion services. Phase 1 of the Hemovigilance Unit's activities consist of performing retrospective chart reviews on patients identified through the Unit monitoring system as having a possible transfusion reaction. Any patients identified as having a definite reaction receive a written consult, recorded in the EHR, from a Transfusion Medicine Physician. May 20, 2019. Following a 2-4 week prospective pilot in 3 areas where transfusions are administered (Phase 2), the Hemovigilance Unit will track the vital signs of each patient receiving transfusion services in real time (Phase 3). These vital signs will be reviewed by an RN under the supervision of an APP or physician 24/7 to			

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	complement the monitoring being provided at the bedside. The real time monitoring will also weight the vital signs and assign a risk number for each patient that is updated in real time, highlighting patients exhibiting potential signs of a reaction. Signs of a reaction will be referred to a member of the transfusion medicine practice. In addition to the monitoring being done by nursing under this POC, the Hemovigilance Unit will also review potential false negatives on an ongoing basis and report to the Transfusion and Patient Blood Management Committee. We are not formally submitting Phase 2 and 3 as part of our corrective action as these require a significant time investment to operationalize it across the hospital but we wanted CMS to be aware of its development as proof of our commitment to being an industry leader in developing new, innovative approaches to delivering the highest level of care. This plan of correction is also addressed under the Plans of Correction Tags A 043, A 144, A 385, and A 115.			
A 409(D)	The Hospital ensures that nurses have complete and accurate orders prior to initiating transfusions. Blood components are infused at the duration specified in the Credentialed Provider orders for transfusion. Orders are clarified as needed, and Credentialed Providers are notified if the orders are not followed. A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including	All RNs who administer blood components received pertinent education and training with knowledge assessment to be completed by July 10, 2019. The topics addressed during the training included changes to the EHR Blood Component Order Sets, adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, Patient Care Orders Policy CLN1140, and Stop the Line for Patient Safety Policy CLN1185, obtaining complete and accurate Credentialed Provider orders prior to initiating transfusions, infusing blood components at the duration specified in the Credentialed Provider order	A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by the OPI to determine adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, EHR Credentialed Provider Order Sets, and Stop The Line DCLN1185, specifically that orders specify the duration for the transfusion, and the actual duration of the transfusion. OPI reviews the data with the Executive Director of Nursing	Chief Nursing Officer Completion Date: July 10, 2019

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	the CMS/CLIA Steering Committee, members of the Transfusion and Patient Blood Management Committee, the Multidisciplinary Clinical Policies and Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and Transfusion Reaction Policy CLN1115. As part of this review over 6,000 patient charts who received blood transfusions were reviewed. The Hospital took the following actions to ensure that RNs infuse blood components at the duration specified in the order, that orders are clarified as needed, and that Credentialed Providers are notified if the orders are not followed: (1) The Blood Component Administration and Transfusion Reaction Policy CLN1115 was further modified to require that blood components are administered via volumetric pump to ensure the duration of the transfusion is in accordance with the Credentialed Provider's orders. (Accordingly, blood components will not be administered via "gravity" flow). The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was approved on June 20, 2019. (2) To ensure clarity of Credentialed Provider orders, the Hospital's Patient Care Orders Policy CLN1140 was modified as follows: (i) to require health care providers to seek clarification of incomplete,	for transfusion, clarifying orders as necessary, notifying the Credentialed Provider if orders are not followed, and procedures for stopping the line for patient safety. July 10, 2019. Any RN on leave who transfuses blood components must complete the training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115, Patient Care Orders Policy CLN1140, and Stop the Line for Patient Safety Policy CLN1185, obtaining complete and accurate Credentialed Provider orders prior to initiating transfusions, infusing blood components at the duration specified in the Credentialed Provider order for transfusion, clarifying orders as necessary, notifying the Credentialed Provider if orders are not followed, and procedures for stopping the line for patient safety is included in the on-boarding process for new RNs who transfuse blood components.	Quality, Safety and Research, and the Laboratory Medicine Quality and Safety Officer to develop recommendations for improvement. In collaboration with the Executive Director of Nursing Quality, Safety and Research and the Laboratory Medicine Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and Patient Blood Management Committee, the ECMS, and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council. The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Executive Director of Nursing, Strategy, Practice and Execution and Executive Director of Quality, Safety and Research will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate.	

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	conflicting or unclear orders. The Executive Owner of the Patient Care Orders Policy CLN1140 (the Chief Medical Officer) and the ECMS, approved the updated Patient Care Orders Policy CLN1140, which was published on June 20, 2019. (3) Electronic Health Record (EHR) Credentialed Provider Order Set was modified to require duration of blood component transfusion. A Credentialed Provider must specify the duration of the blood component transfusion in order to complete the blood component order (hard stop). This change will be effective by July 10, 2019. (4) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone to stop the line for an incomplete, conflicting or unclear order or in the event of a suspected transfusion reaction. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Stop the Line for Patient Safety Policy CLN1185, which was approved on June 20, 2019. Training was developed by the Executive Director of Nursing, Professional Practice, Strategy and Execution to develop curriculum and implement training for registered nurses (RN) who administer blood components pursuant to the Blood Component Administration and Transfusion Reaction Policy CLN1115, the Stop The Line for Patient Safety Policy CLN 1185, the Patient Care Orders Policy CLN			

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	1140, and the EHR Order Set. This plan of Correction is also addressed under Plan of Correction Tag A385.			
A 409(E)	The Hospital ensures that nurses follow Credentialed Provider orders for transfusion rates (duration) for patients. A transfusion reaction investigation was completed regarding the Reference Patient. An interdisciplinary team including the CMS/CLIA Steering Committee, members of the Transfusion and Patient Blood Management Committee, the Multidisciplinary Clinical Policies and Procedures Task Force, Medical Staff and Nursing reviewed the Hospital's Blood Component Administration and Transfusion Reaction Policy CLN1115. As part of this review over 6,000 patient charts who received blood transfusions were reviewed. The Hospital took the following actions to ensure complete and accurate orders for blood components, that RNs infuse blood components at the duration specified in the order, that orders are clarified as needed, and that Credentialed Providers are notified if the orders are not followed: (1) The Blood Component Administration and Transfusion Reaction Policy CLN1115 was further modified to require that blood components are administered via volumetric pump to ensure the duration of the transfusion is in accordance with the Credentialed Provider's orders. (Accordingly, blood components will not be administered via "gravity" flow).	All RNs who administer blood components received pertinent education and training with knowledge assessment to be completed by July 10, 2019. The topics addressed during the training included changes to the EHR Blood Component Order Sets, adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, Patient Care Orders Policy CLN1140, and Stop the Line for Patient Safety Policy CLN1185, obtaining complete and accurate Credentialed Provider orders prior to initiating transfusions, infusing blood components at the duration specified in the Credentialed Provider order for transfusion, clarifying orders as necessary, notifying the Credentialed Provider if orders are not followed, and procedures for stopping the line for patient safety. July 10, 2019. Any RN on leave who transfuses blood components must complete the training before attending patients. Education regarding Blood Component Administration and Transfusion Reaction Policy CLN1115, Patient Care Orders Policy CLN1140, and Stop the Line for Patient Safety Policy CLN1185, obtaining complete and accurate Credentialed Provider orders prior to initiating transfusions, infusing blood components at the duration specified in the Credentialed Provider order for transfusion, clarifying orders as necessary, notifying the Credentialed Provider if orders are not followed, and procedures for stopping the line for patient safety is included in the on-boarding process for new RNs who transfuse blood components.	A random sample of 93 blood component transfusion records are audited and analyzed retrospectively each week by the OPI to determine adherence to Blood Component Administration and Transfusion Reaction Policy CLN1115, EHR Credentialed Provider Order Sets, and Stop The Line DCLN1185, specifically that orders specify the duration for the transfusion, and the actual duration of the transfusion. OPI reviews the data with the Executive Director of Nursing Quality, Safety and Research, and the Laboratory Medicine Quality and Safety Officer to develop recommendations for improvement. In collaboration with the Executive Director of Nursing Quality, Safety and Research and the Laboratory Medicine Quality and Safety Officer, OPI will submit the information and recommendations for improvement to the Transfusion and Patient Blood Management Committee, the ECMS, and the QAPI Council monthly for at least 2 months. After 2 months of data collection, the QAPI Council will determine whether the frequency of data collection should be adjusted (up or down) based on performance. The Transfusion and Patient Blood Management Committee and ECMS will review the determination and may make recommendations for further improvement to the QAPI Council.	Chief Nursing Officer Completion Date: July 10, 2019

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	The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Blood Component Administration and Transfusion Reaction Policy CLN1115, which was approved on June 20, 2019. (2) To ensure clarity of Credentialed Provider orders, the Hospital's Patient Care Orders Policy CLN1140 was modified as follows: (i) to require health care providers to seek clarification of incomplete, conflicting or unclear orders. The Executive Owner of the Patient Care Orders Policy CLN1140 (the Chief Medical Officer) and the ECMS, approved the updated Patient Care Orders Policy CLN1140, which was published on June 20, 2019. (3) Electronic Health Record (EHR) Credentialed Provider Order Set was modified to require duration of blood component transfusion. A Credentialed Provider must specify the duration of the blood component transfusion in order to complete the blood component order (hard stop). This change will be effective by July 10, 2019. (4) Stop the Line for Patient Safety Policy CLN1185 was modified to permit anyone to stop the line for an incomplete, conflicting or unclear order or in the event of a suspected transfusion reaction. The Executive Owner of the Policy (the Chief Medical Officer) and the ECMS, approved the updated Stop the Line for		The QAPI Council will provide a summation to the ELT and the Governing Body at least quarterly. The Executive Director of Nursing, Strategy, Practice and Execution and Executive Director of Quality, Safety and Research will address any deficiencies with the individual nursing staff member through pertinent education and training, re-education and/or disciplinary action, as appropriate.	

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	Patient Safety Policy CLN1185, which was approved on June 20, 2019. Training was developed by the Executive Director of Nursing, Professional Practice, Strategy and Execution to develop curriculum and implement training for registered nurses (RN) who administer blood components pursuant to the Blood Component Administration and Transfusion Reaction Policy CLN1115, the Stop The Line for Patient Safety Policy CLN 1185, the Patient Care Orders Policy CLN 1140, and the EHR Order Set. This plan of correction is also addressed under Plan of Correction Tag A385.			
Tag A 576	A. The Division Quality Management Plan (DIV QIP 0206) has been renamed CLIA Laboratory Quality Management Plan and has been revised to require that the quality data from all 25 laboratory sections/areas be reported to the ECMS and the QAPI Council on a monthly basis. June 14, 2019. B. The Division Quality Management Plan (DIV QIP 0206) has been renamed CLIA Laboratory Quality Management Program and has been revised to require that all laboratory sections/areas are identified and required to submit quality data to the ECMS and the QAPI Council.	All applicable Laboratory Directors, each of whom is responsible for different portions of the 25 laboratory sections/areas, will be educated on the revised and renamed CLIA Laboratory Quality Management Plan with a special emphasis on the monthly reporting of quality data for each section/area to the ECMS and the QAPI Council. July 10, 2019	Each Laboratory Director shall delegate responsibility to the Pathology and Laboratory Medicine Division Head for reviewing the quality reports from all laboratory sections/areas on a monthly basis for 6 months to ensure consistent reporting. In the event that any area or section fails to timely report its quality data, the responsible individuals will be retrained and may be subject to discipline in accordance with the hospital's HR policies. Monitoring will continue until all sections/areas are timely reported for a period of 6 months.	Laboratory Director Completion Date: July 10, 2019