

Prepublication Requirements

• Issued February 21, 2023 •



Revisions to the Patient Blood Management Program

The Joint Commission has approved the following revisions for prepublication. While revised requirements are published in the semiannual updates to the print manuals (as well as in the online *E-dition*®), accredited organizations and paid subscribers can also view them in the monthly periodical *The Joint Commission Perspectives*®. To begin your subscription, call 800-746-6578 or visit <http://www.jcrinc.com>.

Please note: Where applicable, this report shows current standards and EPs first, with deleted language struck-through. Then, the revised requirement follows in bold text, with new language underlined.

APPLICABLE TO THE PATIENT BLOOD MANAGEMENT CERTIFICATION PROGRAM

Effective July 1, 2023

Assessments: Internal and External (PBMAM) Chapter

PBMAM.01

The program performs internal and external assessments of operations and quality systems.

Element(s) of Performance for PBMAM.01

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| 3. | The results of internal and external assessments are provided to and reviewed by personnel having responsibility for the area being assessed. | <input type="checkbox"/> D |
| 3. | The results of internal and external assessments are provided to and reviewed by personnel <u>responsible</u> for the area being assessed. | <input type="checkbox"/> D |

PBMAM.02

The program reports on its performance.

Element(s) of Performance for PBMAM.02

Key: **D** indicates that documentation is required;

R indicates an identified risk area;

2. The report includes the following, ~~at a minimum~~, if required for the program's activity level: D
- Overall program effectiveness and opportunities for improvement.
 - Allogeneic transfusion rates overall and by program defined high blood use groups.
 - Appropriateness of allogeneic transfusion overall and by program defined high blood use groups.
 - Blood and blood component discard and cause(s) of waste.
 - Use and efficacy of preoperative anemia management interventions.
 - Effectiveness of nonoperative anemia management.
 - Use and effectiveness of the emergency/massive transfusion processes and protocols.
 - Compliance with recommendations made by the program.
 - ~~- Transfusion-associated adverse events and adverse events associated with the failure to transfuse.~~
 - Program financial impact.
 - Program performance goals and other needs for next reporting period.
- Note: For more information on a program's activity level, refer to Appendix A.

2. The report includes, but is not limited to the following, if required for the program's activity level: D
- Overall program effectiveness and opportunities for improvement.
 - Allogeneic transfusion rates overall and by program defined high blood use groups.
 - Appropriateness of allogeneic transfusion overall and by program defined high blood use groups.
 - Blood and blood component discard and cause(s) of waste.
 - Use and efficacy of preoperative anemia management interventions.
 - Use of perioperative blood management techniques.
 - Effectiveness of nonoperative anemia management.
 - Use and effectiveness of the emergency/massive transfusion/massive hemorrhage processes and protocols.
 - Compliance with recommendations made by the program.
 - Adverse events associated with patient blood management activities.
 - Program financial impact.
 - Program performance goals and other needs for next reporting period.
- Note: For more information on a program's activity level, refer to Appendix A.

Deviations, Nonconformances and Adverse Events (PBMDN) Chapter

PBMDN.01

The program captures, investigates, and reports deviations, nonconformances, and adverse events.

Element(s) of Performance for PBMDN.01

1. The program has policies, processes, and procedures to ~~ensure the capture, assessment, investigation, and monitoring~~ of deviations from meeting, or failing to meet, specified requirements. (D)

Note: Specified requirements are any requirements in these PBM standards and including, but not limited to, US Food and Drug Administration (FDA) requirements; requirements of a facility's internal policies, processes, and procedures; manufacturers' instructions; customer agreements; practice standards; and requirements of accrediting organizations such as AABB and The Joint Commission.

1. **The program has policies, processes, and procedures to capture, assess, investigate, and monitor deviations from meeting, or failing to meet, specified requirements.** (D)

Note: Specified requirements are any requirements in these PBM standards and including, but not limited to, US Food and Drug Administration (FDA) requirements; requirements of a facility's internal policies, processes, and procedures; manufacturers' instructions; customer agreements; practice standards; and requirements of accrediting organizations such as AABB and The Joint Commission.

PBMDN.02

The program captures and evaluates nonconformances.

Element(s) of Performance for PBMDN.02

2. The program has a process for ~~the capture of~~ nonconformances related to these PBM standards. (D)

2. **The program has a process for capturing the nonconformances related to these PBM standards.** (D)

Documents and Records (PBMDR) Chapter

PBMDR.03

The program has a process for record retention.

Element(s) of Performance for PBMDR.03

3. Before the destruction of the original records, the program has a process to ensure that copies of records are as follows:
- Verified as containing the original content.
 - Legible, complete, and accessible.

3. **Before the destruction of the original records, the program has a process to ensure that copies of records are as follows:**
- **Verified as containing the original content.**
 - **Legible, indelible, complete, and accessible.**
 - **Identified as a copy.**

PBMDR.04

The program has a record system.

Element(s) of Performance for PBMDR.04

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

4. Information in the record system allows the program to trace any patient from the preoperative/pretransfusion period to the postoperative/posttransfusion period, as well as trace the care of and blood management services provided to the patient.

4. **Information in the record system allows the program to trace any patient from the preoperative/pretransfusion period to the postoperative/posttransfusion period, and trace the care of and blood management services provided to the patient.**

PBMDR.06

The program is involved in the development of policies, processes, and procedures that affect the quality of the program's activities.

Element(s) of Performance for PBMDR.06

1. The program participates in the development of new policies and in changes to existing policies, processes, and procedures that affect the quality of the program's activities, even when these documents are controlled by another department.

1. **The program participates in the development of new policies and in changes to existing policies, processes, and procedures that affect the quality of the program's activities, even when another department controls these documents.**

PBMDR.07

The program retains records of program activities. (See also Appendix B)

Element(s) of Performance for PBMDR.07

1. **Records of the delegation of medical director responsibilities to another qualified individual(s) are retained for a minimum of 5 years.**

4. ~~The following records are retained for a minimum of 5 years: Management review of the effectiveness of the quality system.~~

2. **Records of management reviews of the effectiveness of the quality system are retained for a minimum of 5 years.**

2. ~~The following records are retained for a minimum of 5 years: Emergency management plan review.~~

3. **Emergency management plan review records are retained for a minimum of 5 years.**

3. ~~The following records are retained for a minimum of 5 years: Job descriptions.~~

4. **Job descriptions are retained for a minimum of 5 years.**

4. ~~The following records are retained for a minimum of 5 years: Qualification of personnel performing activities affecting quality.~~

5. **Qualification records of personnel performing activities affecting quality are retained for a minimum of 5 years.**

Key: **(D)** indicates that documentation is required; **(R)** indicates an identified risk area;

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| 5. The following records are retained for a minimum of 5 years: Evaluations of competence. | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. <u>Evaluation of competence records are retained for a minimum of 5 years.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. The following records are retained for a minimum of 5 years: Personnel records of patient blood management program employees. | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. <u>Personnel records of patient blood management program employees are retained for a minimum of 5 years.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. The following records are retained for a minimum of 5 years: Facility-defined educational requirements for individuals who order and/or transfuse blood. | <input type="checkbox"/> | <input checked="" type="checkbox"/> (D) |
| 8. <u>Facility-defined educational requirements for individuals who order and/or transfuse blood are retained for a minimum of 5 years.</u> | <input type="checkbox"/> | <input checked="" type="checkbox"/> (D) |
| 8. The following records are retained for a minimum of 5 years: Evaluation and participation in selection of suppliers of products and patient blood management-related services. | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. <u>Records of the implementation of new or modified software, hardware, or databases and modifications of existing software, hardware, or databases are retained for a minimum of 2 years after the retirement of the system.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. The following records are retained for a minimum of 5 years: Agreements. | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. <u>Information system records are retained for a minimum of 2 years after the retirement of the system, including the following:</u>
<u>- Validation of system software, hardware, databases, and user-defined tables</u>
<u>- Fulfillment of applicable life-cycle requirements</u>
<u>- Numerical designation of system versions, if applicable, with inclusive dates of use</u>
<u>- Monitoring of data integrity for critical data elements</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. The following records are retained for a minimum of 5 years: Review of agreements. | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. <u>Records of the evaluation and participation in selection of suppliers of products components and patient blood management-related services are retained for a minimum of 5 years.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. The following records are retained for a minimum of 5 years: Validation of new or changed processes and procedures. | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. <u>Agreement records are retained for a minimum of 5 years.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. The following records are retained for a minimum of 5 years: Review of blood management and utilization practices. | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. <u>Records of the review of agreements are retained for a minimum of 5 years.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. The following records are retained for a minimum of 5 years: Blood management educational materials. | <input type="checkbox"/> | <input type="checkbox"/> |

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| <u>14. Records of the validation of new or changed processes and procedures are retained for a minimum of 5 years.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. The following records are retained for a minimum of 5 years: Review of quality control results for patient blood management-related equipment and methods. | <input type="checkbox"/> | <input type="checkbox"/> |
| <u>15. Records of the review of blood management and utilization practices are retained for a minimum of 5 years.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. The following records are retained for a minimum of 5 years: Patient consent. | <input type="checkbox"/> | <input type="checkbox"/> |
| <u>16. Blood management education materials are retained for a minimum of 5 years.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 16. The following records are retained for a minimum of 5 years: Alternative strategies acceptable to patients who decline blood. | <input type="checkbox"/> | <input type="checkbox"/> |
| <u>17. Records of the review of quality control results for patient blood management-related equipment and methods are retained for a minimum of 5 years.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 17. The following records are retained for a minimum of 5 years: Review and approval of new and revised documents before use. | <input type="checkbox"/> | <input type="checkbox"/> |
| <u>18. Patient consent records are retained for a minimum of 5 years.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 18. The following records are retained for a minimum of 5 years: Biennial review of policies, processes, and procedures. | <input type="checkbox"/> | <input type="checkbox"/> |
| <u>19. Records of alternative strategies acceptable to patients who decline blood are retained for a minimum of 5 years.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 19. The following records are retained for a minimum of 5 years: Identification and appropriate archival of obsolete documents. | <input type="checkbox"/> | <input type="checkbox"/> |
| <u>20. Records of the review and approval of new and revised documents before use are retained for a minimum of 5 years.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 20. The following records are retained for a minimum of 5 years: Description and evaluation of nonconformances. | <input type="checkbox"/> | <input type="checkbox"/> |
| <u>21. Records of the biennial review of policies, processes, and procedures are retained for a minimum of 5 years.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 21. The following records are retained for a minimum of 5 years: Reviews of results of internal and external assessments and associated corrective and preventive action. | <input type="checkbox"/> | <input type="checkbox"/> |
| <u>22. Records of the identification and appropriate archival of obsolete documents are retained for a minimum of 5 years.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 22. The following records are retained for a minimum of 5 years: Implementation of changes to policies, processes, and procedures resulting from corrective and preventive action. | <input type="checkbox"/> | <input type="checkbox"/> |

Key: **(D)** indicates that documentation is required; **(R)** indicates an identified risk area;

23. Records of the description and evaluation of nonconformances are retained for a minimum of 5 years.

~~23. The following records are retained for a minimum of 5 years: Corrective action.~~

24. Records of the reviews of results of internal and external assessments and associated corrective and preventive action are retained for a minimum of 5 years.

~~24. The following records are retained for a minimum of 5 years: Preventive action.~~

25. Records of the implementation of changes to policies, processes, and procedures resulting from corrective and preventive action are retained for a minimum of 5 years.

~~25. The following records are retained for a minimum of 2 years after retirement of the system: Implementation of new or modified software, hardware, or databases and modifications of existing software, hardware, or databases.~~

26. Records of corrective actions are retained for a minimum of 5 years.

~~26. The following records are retained for a minimum of 2 years after retirement of the system: Information systems records that include the following:
 –Validation of system software, hardware, databases, and user-defined tables.
 –Fulfillment of applicable life-cycle requirements.
 –Numerical designation of system versions, if applicable, with inclusive dates of use.
 –Monitoring of data integrity for critical data elements.~~

27. Records of preventative actions are retained for a minimum of 5 years.

Equipment (PBMEQ) Chapter

PBMEQ.01

The program manages its medical equipment.

Element(s) of Performance for PBMEQ.01

~~3. The program has input in the acquisition of equipment needed to perform the activities defined in these PBM standards.~~

3. The program has input in acquisition decisions regarding equipment necessary to perform the activities defined in these PBM standards.

PBMEQ.04

The program maintains an alternate information management system.

The program maintains an alternative (backup) information management system.

Element(s) of Performance for PBMEQ.04

Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

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| 1. An alternate (backup) system is maintained to ensure continuous operation in the event that computerized data and computer-assisted functions are unavailable. | <input type="checkbox"/> <input type="checkbox"/> |
| 1. An alternative (backup) system is maintained to ensure continuous operation in the event that computerized data and computer-assisted functions are unavailable. | <input type="checkbox"/> <input type="checkbox"/> |
| 2. The alternate system is tested periodically. | <input type="checkbox"/> <input type="checkbox"/> (D) |
| 2. The alternative (backup) system is tested periodically. | <input type="checkbox"/> <input type="checkbox"/> (D) |
| 4. The program has a process in place to minimize the risk and impact of an internal or external data breach. | <input type="checkbox"/> <input type="checkbox"/> (D) |

PBMEQ.05

The program defines quality control activities for equipment controlled by other departments.

Element(s) of Performance for PBMEQ.05

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| 2. Equipment controlled by the blood bank, transfusion service, clinical laboratory, or perioperative program are controlled in accordance with the manufacturer's written instructions and/or the current editions of AABB Standards for Blood Banks and Transfusion Services and AABB Standards for Perioperative Autologous Blood Collection and Administration. | <input type="checkbox"/> <input type="checkbox"/> |
| 2. Equipment controlled by the blood bank, transfusion service, clinical laboratory, or perioperative program are operated in accordance with the manufacturer's written instructions and/or the current editions of AABB Standards for Blood Banks and Transfusion Services and AABB Standards for Perioperative Autologous Blood Collection and Administration. | <input type="checkbox"/> <input type="checkbox"/> |

Facilities and Safety (PBMFS) Chapter

PBMFS.01

The program provides safe environmental conditions.

Element(s) of Performance for PBMFS.01

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| 1. The program adheres to the facility's policies, processes, and procedures for the provision of safe environmental conditions. | <input type="checkbox"/> <input type="checkbox"/> |
| 1. The program adheres to the facility's policies, processes, and procedures to provide safe environmental conditions. | <input type="checkbox"/> <input type="checkbox"/> |

Organization (PBMOR) Chapter

PBMOR.01

The program has a defined organizational structure.

Element(s) of Performance for PBMOR.01

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

2. The interdisciplinary program is patient centered, data driven, and outcomes focused.
2. **The interdisciplinary program is patient centered, evidence based, data driven, and outcomes focused.**

PBMOR.02

The program defines the roles and responsibilities of the executive management team.

Element(s) of Performance for PBMOR.02

2. Executive management has:
- The responsibility and authority for oversight and review of the program.
 - The authority to establish or ~~make changes to~~ the program's quality system.
 - The responsibility for compliance with these PBM standards and applicable laws and regulations.
 - The responsibility for ~~collection and review of~~ data on patient blood management including patient outcomes and program performance metrics.
 - The responsibility to identify stakeholders and to communicate results to these stakeholders.
2. **Executive management has:**
- **The responsibility and authority for oversight and review of the program.**
 - **The authority to establish or change the program's quality system.**
 - **The responsibility for compliance with these PBM standards and applicable laws and regulations.**
 - **The responsibility for collecting and reviewing data on patient blood management including patient outcomes and program performance metrics.**
 - **The responsibility to identify stakeholders and to communicate results to these stakeholders.**

PBMOR.03

The program defines the roles and responsibilities of the medical director.

Element(s) of Performance for PBMOR.03

1. The program has a medical director who is a licensed ~~physician~~ and qualified by education, training, and/or experience.
1. **The program has a medical director who is a licensed practitioner and qualified by education, training, and/or experience.**

PBMOR.04

The executive management defines, oversees, and monitors the activities of the program.

Note: A patient blood management program can be designated as a program activity level 1, 2, or 3. To be designated a specific activity level, the program is responsible for or has direct involvement with oversight and monitoring of the various activities defined in PBMOR.4, EPs 2–25. For more information on a program's activity level, refer to Appendix A.

Element(s) of Performance for PBMOR.04

Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

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| 2. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities : Evidence of institutional support for the patient blood management program at the hospital administration level. | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. The program is responsible for, or has direct involvement with, oversight and monitoring of the evidence of institutional support for the patient blood management program at the hospital administration level. | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities : Metrics regarding transfusion appropriateness in accordance with transfusion guidelines. | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. The program is responsible for, or has direct involvement with, oversight and monitoring of metrics regarding transfusion appropriateness <u>consistent</u> with transfusion guidelines. | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities : Documentation of transfusion including patient consent, observation, adverse events, and outcomes. | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. The program is responsible for, or has direct involvement with, oversight and monitoring of the documentation of transfusion including patient consent, observation, adverse events, and outcomes. | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities : Budgeting to the level of care required by the implementation of these PBM standards. | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. The program is responsible for, or has direct involvement with, oversight and monitoring of budgeting to the level of care required by the implementation of these PBM standards. | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities : Pretransfusion patient testing and evaluation. | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. The program is responsible for, or has direct involvement with, oversight and monitoring of pretransfusion patient testing and evaluation. | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities : Patient- or case-specific assessment of potential blood usage. | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. The program is responsible for, or has direct involvement with, oversight and monitoring of patient- or case-specific assessment of potential blood usage. | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities : Preprocedural blood ordering including completion of type and antibody testing before procedure start time with a plan for antibody-positive patients. | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. The program is responsible for, or has direct involvement with, oversight and monitoring of preprocedural blood ordering including completion of type and antibody testing before procedure start time with a plan for antibody-positive patients. | <input type="checkbox"/> | <input type="checkbox"/> |

Key: **(D)** indicates that documentation is required;

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| 9. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities: Preprocedure optimization of patient coagulation function. | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. The program is responsible for, or has direct involvement with, oversight and monitoring of <u>preprocedure assessment and management of patient coagulation status.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities: Monitoring of blood components wastage and cause. | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. The program is responsible for, or has direct involvement with, oversight and monitoring of <u>blood components wastage and cause.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities: Minimize blood loss due to laboratory testing. | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. The program is responsible for, or has direct involvement with, oversight and monitoring of <u>activities to minimize blood loss due to laboratory testing (iatrogenic blood loss).</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities: Process for managing the blood needs of unidentified patients and resolving their identification. | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. The program is responsible for, or has direct involvement with, oversight and monitoring of the <u>process for managing the blood needs of unidentified patients and resolving their identification.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities: Processes to identify, before or upon admission, patients who may decline transfusion under any circumstances with notification to the appropriate individuals. | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. The program is responsible for, or has direct involvement with, oversight and monitoring of the <u>processes to identify, before or upon admission, patients who may decline transfusion with notification to the appropriate individuals (including providers) and noted in the patient's medical record.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities: Massive transfusion protocol with documented evidence of its use. | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. The program is responsible for, or has direct involvement with, oversight and monitoring of <u>massive transfusion/massive hemorrhage protocol for all patient populations with documented evaluation of activation and protocol workflow effectiveness and evidence of its use, transfusion protocol use and compliance.</u> | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities: Transfusion care and anemia management of preterm, neonate, infant, and pediatric critical care patients, if applicable. | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. The program is responsible for, or has direct involvement with, oversight and monitoring of <u>transfusion care and anemia management of preterm, neonate, infant, and pediatric critical care patients, if applicable.</u> | <input type="checkbox"/> | <input type="checkbox"/> |

Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

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| 16. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities: Patient blood management care for obstetrics patients including postpartum hemorrhage protocol with evidence of its use, plan(s) for patients with known high bleeding risk (e.g. placental abnormalities), and plans for patients for whom blood is not an option. | <input type="checkbox"/> | <input type="checkbox"/> |
| 16. The program is responsible for, or has direct involvement with, oversight and monitoring of patient blood management care for obstetric patients including postpartum hemorrhage protocol with evidence of its use, plan(s) for patients with known high bleeding risk (e.g. placental abnormalities), and plans for patients for <u>where</u> blood is not an option. | <input type="checkbox"/> | <input type="checkbox"/> |
| 17. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities: Single-unit transfusion strategies for defined patient population(s). | <input type="checkbox"/> | <input type="checkbox"/> |
| 17. The program is responsible for, or has direct involvement with, oversight and monitoring of single-unit transfusion strategies for defined <u>clinical settings</u>. | <input type="checkbox"/> | <input type="checkbox"/> |
| 18. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities: Management of acquired coagulopathy. | <input type="checkbox"/> | <input type="checkbox"/> |
| 18. The program is responsible for, or has direct involvement with, oversight and monitoring of activities to <u>manage</u> acquired coagulopathy. | <input type="checkbox"/> | <input type="checkbox"/> |
| 19. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities: Blood conservation strategies for service lines associated with high blood usage. | <input type="checkbox"/> | <input type="checkbox"/> |
| 19. The program is responsible for, or has direct involvement with, oversight and monitoring of blood conservation strategies for service lines associated with high blood usage. | <input type="checkbox"/> | <input type="checkbox"/> |
| 20. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities: Processes and/or equipment to facilitate rapid decision making with regard to anemia and coagulation management. | <input type="checkbox"/> | <input type="checkbox"/> |
| 20. The program is responsible for, or has direct involvement with, oversight and monitoring of processes and/or equipment to facilitate rapid decision making <u>concerning</u> anemia and coagulation management. | <input type="checkbox"/> | <input type="checkbox"/> |
| 21. The program is be responsible for, or has direct involvement with, oversight and monitoring of the following activities: Evaluating and managing iron and micronutrient deficiencies in defined patients with red blood cells ordered in the outpatient setting. | <input type="checkbox"/> | <input type="checkbox"/> |
| 21. The program is be responsible for, or has direct involvement with, oversight and monitoring of evaluating and managing iron and micronutrient deficiencies in defined patients with red blood cells ordered in the <u>inpatient and outpatient</u> populations. | <input type="checkbox"/> | <input type="checkbox"/> |
| 22. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities: Evaluation and management of anemia in nonoperative patients. | <input type="checkbox"/> | <input type="checkbox"/> |
| 22. The program is responsible for, or has direct involvement with, oversight and monitoring of the evaluation and management of <u>identified</u> anemia in patients. | <input type="checkbox"/> | <input type="checkbox"/> |

Key: **(D)** indicates that documentation is required; **(R)** indicates an identified risk area;

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| 23. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities: A program to care for patients who decline use of blood or blood-derived components. | <input type="checkbox"/> <input type="checkbox"/> |
| 23. The program is responsible for, or has direct involvement with, oversight and monitoring of a <u>protocol</u> to care for patients who decline use of blood or blood-derived components. | <input type="checkbox"/> <input type="checkbox"/> |
| 24. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities: Identification and management of presurgical anemia before elective procedures for which type and screen or type and crossmatch is recommended. | <input type="checkbox"/> <input type="checkbox"/> |
| 24. The program is responsible for, or has direct involvement with, oversight and monitoring of the identification and management of presurgical anemia before elective procedures for <u>patients at risk for red blood cell transfusion and/or adverse consequences of post-surgical anemia.</u> | <input type="checkbox"/> <input type="checkbox"/> |
| 25. The program is responsible for, or has direct involvement with, oversight and monitoring of patient blood management care for patients undergoing cardiac surgery or structural heart procedures. | <input type="checkbox"/> <input type="checkbox"/> |
| 25. The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities: Use of perioperative techniques consistent with current AABB Standards for Perioperative Autologous Blood Collection and Administration. | <input type="checkbox"/> <input type="checkbox"/> |
| 26. The program is responsible for, or has direct involvement with, oversight and monitoring of the use of perioperative techniques consistent with current AABB Standards for Perioperative Autologous Blood Collection and Administration. | <input type="checkbox"/> <input type="checkbox"/> |

PBMOR.06

The program has a patient-centered quality plan.

Element(s) of Performance for PBMOR.06

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| 1. A patient-centered quality plan is defined, documented, implemented, and maintained in order to ensure reliability and reproducibility and to optimize patient outcomes. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| 1. A patient-centered quality plan is defined, documented, implemented, and maintained <u>to ensure reliability and reproducibility and optimize patient outcomes.</u> | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| 4. The quality plan encompasses all of the relevant policies, processes, procedures, protocols, and other work documents related to the treatment of patients who may receive a blood transfusion, decline blood transfusion, or are managed in accordance with the activity level.
Note: For more information on a program's activity level, refer to Appendix A. | <input type="checkbox"/> <input type="checkbox"/> |
| 4. The quality plan encompasses all of the relevant policies, processes, procedures, protocols, and other work documents related to <u>treating</u> patients who may receive a blood transfusion, decline blood transfusion, or are managed <u>per</u> the activity level.
Note: For more information on a program's activity level, refer to Appendix A. | <input type="checkbox"/> <input type="checkbox"/> |

PBMOR.09

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

The program has policies, processes, and procedures for operational continuity.

Element(s) of Performance for PBMOR.09

2. The program has policies, processes, and procedures to define and address critical supplies, equipment, and product inventory shortages.

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PBMOR.10

The program has a process to communicate concerns about quality and safety.

Element(s) of Performance for PBMOR.10

1. The program has a process for personnel to anonymously communicate concerns about quality or safety.
2. Personnel are given the option to communicate such concerns either to their facility's executive management, The Joint Commission, or both.
3. The Joint Commission's contact information is readily available to all personnel.

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Process Control (PBMPC) Chapter

PBMPC.01

The program develops and implements policies and procedures.

Element(s) of Performance for PBMPC.01

4. Program policies address patients who decline blood transfusion.
4. **Program policies address patients for whom blood transfusion is not an option.**
8. The program has policies, processes, and procedures to ensure that:
 - Patients who may need transfusion are evaluated and managed such that blood is given when clinically indicated.
 - Internal quality metrics for transfusion appropriateness are in place and reported.
 - Patients with anemia who may or may not need a transfusion are also assessed for other means by which it may be managed, including by minimizing bleeding and treating anemia with medications.
8. **The program has policies, processes, and procedures to ensure that:**
 - **Patients who may need transfusion are evaluated and managed such that blood is given when clinically indicated.**
 - **Internal quality metrics for transfusion appropriateness are in place and reported.**
 - **Patients with anemia who may or may not need a transfusion are also assessed for other means by which it may be managed, including by minimizing bleeding and treating anemia with medications.**
 - **Patients with or at risk for coagulopathy are evaluated and managed.**

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PBMPC.02

Key: ⓓ indicates that documentation is required;

Ⓜ indicates an identified risk area;

The program develops new or changes existing processes or procedures.

Element(s) of Performance for PBMPC.02

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| 2. | The process to develop new processes or procedures or to change existing ones include identification of specifications and verification that specifications have been met. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| 2. | The process to develop new processes or procedures or to change existing ones includes the identification of specifications and verification that specifications have been met. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |

PBMPC.03

The program has patient blood management guidelines.

Element(s) of Performance for PBMPC.03

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|--|---|--|
| 1. | The program establishes evidence-based (when available) patient blood management guidelines specific to the hospital's inpatient and outpatient populations. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| 1. | The program utilizes evidence-based patient blood management guidelines specific to the hospital's inpatient and outpatient populations. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| 2. | The patient blood management guidelines include practices to avoid transfusion when possible and ensure early and rapid delivery of blood components to those who need them. | <input type="checkbox"/> <input type="checkbox"/> |
| 2. | The patient blood management guidelines include practices to avoid unnecessary transfusion and ensure early and rapid delivery of blood components to those who need them. | <input type="checkbox"/> <input type="checkbox"/> |
| 3. | The patient blood management guidelines shall include managing anemia through transfusion and other methods, including minimizing blood loss, recovery and autotransfusion of shed blood, and managing asymptomatic anemia with medications, as laboratory data support and in accordance with activity level. | <input type="checkbox"/> <input type="checkbox"/> |
| Note: For more information on a program's activity level, refer to Appendix A. | | |
| 3. | The patient blood management guidelines include, but are not limited to:
<u>- Managing anemia and coagulopathy</u>
<u>- Minimizing blood loss and promoting blood recovery</u>
<u>- Managing asymptomatic anemia without the use of blood components according to activity level</u>
Note: For more information on a program's activity level, refer to Appendix A. | <input type="checkbox"/> <input type="checkbox"/> |
| 4. | Guidelines from major patient groups within the facility (service lines, care pathways) are reviewed to ensure consideration of optimal patient blood management. | <input type="checkbox"/> <input type="checkbox"/> |
| 4. | Guidelines from major patient groups within the facility (service lines, care pathways) are reviewed to ensure adherence to patient blood management practices. | <input type="checkbox"/> <input type="checkbox"/> |

PBMPC.04

The program reviews patient blood management practices.

Element(s) of Performance for PBMPC.04

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

2. The program reviews all nonconformances, deviations from established procedures or protocol, and other incidents where ~~transfusion~~ guidelines are not followed. The "Deviations, Nonconformances, and Adverse Events" (PBMDN) and the "Process Improvement Through Corrective and Preventive Action" (PBMPI) chapters apply. ☐ (D)
2. **The program reviews all nonconformances, deviations from established procedures or protocol, and other incidents where patient blood management guidelines are not followed.** The "Deviations, Nonconformances, and Adverse Events" (PBMDN) and the "Process Improvement Through Corrective and Preventive Action" (PBMPI) chapters apply. ☐ (D)

PBMPC.05

The program has educational materials.

Element(s) of Performance for PBMPC.05

1. The program develops and distributes educational materials for hospital personnel and patients that provide the following information: ☐ (D)
- Describe patient blood management ~~elements~~ in the facility including, and as relevant to activity level, general patient blood management and any or all of patient blood management in pediatrics, obstetrics, and outpatients.
 - Describe anemia management in perioperative patients.
 - Describe anemia management in medical patients.
 - Discuss the risks and benefits of transfusion of blood components and transfusion avoidance.
 - Review the alternatives to transfusion, including pharmacological therapies.
- Note: For more information on a program's activity level, refer to Appendix A.
1. **The program develops, reviews, and distributes educational materials at defined intervals for hospital personnel and patients that provide the following information:** ☐ (D)
- Describe patient blood management strategies in the facility including, and as relevant to activity level, general patient blood management and any or all of patient blood management in surgical, pediatric, obstetric, and outpatient.
 - Describe anemia management in perioperative patients.
 - Describe anemia management in medical patients.
 - Describe coagulopathy evaluation and management in surgical patients.
 - Discuss the risks and benefits of transfusion of blood components and transfusion avoidance.
 - Review the alternatives to transfusion, including pharmacological therapies.
- Note: For more information on a program's activity level, refer to Appendix A.

PBMPC.08

The program has policies, processes, and procedures regarding patient consent for transfusion and right to decline transfusion.

Element(s) of Performance for PBMPC.08

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

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|---|---|
| 1. The program participates in the development and revision of policies, processes, and procedures regarding patient consent for transfusion and the right to decline transfusion. | <input type="checkbox"/> <input type="checkbox"/> |
| 1. The program participates in <u>developing and revising</u> policies, processes, and procedures regarding patient consent for transfusion and the right to decline transfusion. | <input type="checkbox"/> <input type="checkbox"/> |
| 2. At a minimum, elements of consent include all of the following:
- A description of the risks, benefits, and treatment alternatives.
- The opportunity to ask and receive answers to the questions.
- The right to accept or refuse treatment. | <input type="checkbox"/> <input type="checkbox"/> |
| 2. At a minimum, elements of consent include all of the following:
- A description of the risks, benefits, and treatment alternatives.
- The opportunity to ask and receive answers to the questions.
- The right to accept or <u>decline</u> treatment. | <input type="checkbox"/> <input type="checkbox"/> |

PBMPC.09

The program has guidelines for transfusion orders.

Element(s) of Performance for PBMPC.09

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| 1. Transfusion orders include indication(s) for transfusion, as determined by program-defined guidelines. | <input type="checkbox"/> <input type="checkbox"/> (D) |
| 1. Transfusion orders include <u>an</u> indication(s) for transfusion, as determined by program-defined guidelines. | <input type="checkbox"/> <input type="checkbox"/> (D) |
| 2. The program has policies for single-unit transfusion strategies for defined patient populations . | <input type="checkbox"/> <input type="checkbox"/> (D) |
| 2. The program has policies for single-unit component transfusion strategies for defined <u>clinical settings</u>. | <input type="checkbox"/> <input type="checkbox"/> (D) |

PBMPC.10

The program has guidelines for pre- and posttransfusion patient care.

Element(s) of Performance for PBMPC.10

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| 2. The program reviews, revises, or creates the policies, processes, and procedures regarding pretransfusion testing . These policies are consistent with the current edition of AABB Standards for Blood Banks and Transfusion Services. | <input type="checkbox"/> <input type="checkbox"/> (D) |
| 2. The program reviews, revises, or creates the <u>pretransfusion testing</u> policies, processes, and procedures. These policies are consistent with the current edition of AABB Standards for Blood Banks and Transfusion Services. | <input type="checkbox"/> <input type="checkbox"/> (D) |
| 5. Situations of overtransfusion or failure to transfuse are identified and evaluated, and a root-cause analysis is performed . | <input type="checkbox"/> <input type="checkbox"/> (D) |
| 5. Situations of <u>over or under transfusion</u> or failure to transfuse are identified and evaluated. | <input type="checkbox"/> <input type="checkbox"/> (D) |

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

PBMPC.11

The program has procedures for preoperative or preintervention patient care.

Element(s) of Performance for PBMPC.11

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|---|--|--|---|
| <p>1. The program shall oversee and review the following:</p> <ul style="list-style-type: none"> - The maximum surgical blood ordering schedule (MSBOS) or equivalent and update if needed. The MSBOS is reviewed at a minimum biennially. - Procedures for identification of patients who refuse transfusion. - Procedures for interventions to minimize the need for allogeneic transfusion. - The prescribing and ordering of appropriate blood components or transfusion-related pharmaceuticals (for example, factor concentrates, antifibrinolytics, hemostatic agents). | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 15px;"></td> <td style="text-align: center;">D</td> </tr> </table> | | D |
| | D | | |
| <p>1. The program shall oversee and review the following:</p> <ul style="list-style-type: none"> - The maximum surgical blood ordering schedule (MSBOS) or equivalent and update if needed. The MSBOS is reviewed at a minimum biennially. - Procedures for identification of patients who <u>decline</u> transfusion. - Procedures for interventions to minimize the need for allogeneic transfusion. - The prescribing and ordering of appropriate blood components or transfusion-related pharmaceuticals (for example, factor concentrates, antifibrinolytics, hemostatic agents). | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 15px;"></td> <td style="text-align: center;">D</td> </tr> </table> | | D |
| | D | | |
| <p>2. For emergent/urgent patients, there are processes and/or procedures for the following:</p> <ul style="list-style-type: none"> - Identification of unknown patients. - Assessment of bleeding risk. - Assessment of patients' physiologic ability to tolerate blood loss. - Timely delivery of blood components. - Interventions to stop bleeding, including the following: <ul style="list-style-type: none"> - Directed interventions including hemostatic agents. - Protocols for rapid reversal of anticoagulants. - Assessment of recovering and reinfusing shed blood. | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 15px;"></td> <td style="text-align: center;">D</td> </tr> </table> | | D |
| | D | | |
| <p>2. For <u>elective procedural/surgical</u> patients, there are processes and/or procedures for the following:</p> <ul style="list-style-type: none"> - <u>Evaluation and management of pre-procedure anemia.</u> - <u>Assurance of safe and effective discontinuation of anticoagulants and/or platelet inhibitors.</u> - Assessment of bleeding risk. - Assessment of patients' physiologic ability to tolerate <u>anemia, iron deficiency, and coagulation systems stress.</u> - <u>Consideration and plan for allogenic blood needs and its alternatives.</u> | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 15px;"></td> <td style="text-align: center;">D</td> </tr> </table> | | D |
| | D | | |

Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

3. For patients undergoing ~~emergent/urgent treatment~~, there shall be processes and/or procedures for the following: (D)
- Identification of unknown patients.
 - Assessment of patients' physiologic ability to tolerate blood loss.
 - Timely delivery of blood components.
 - Interventions to stop bleeding.
 - ~~- Assessment of bleeding risk.~~
 - ~~Consideration of~~ directed interventions including hemostatic agents and protocols for rapid reversal of anticoagulants.
 - Assessment of safely recovering and reinfusing shed blood.
3. For patients undergoing urgent or emergent procedures, there are processes and/or procedures for the following: (D)
- Identification of unknown patients.
 - Assessment of bleeding risk.
 - Assessment of patient for pre-existing anemia and physiologic ability to tolerate blood loss.
 - Timely delivery of blood components.
 - Interventions to stop bleeding, including:
 - Directed interventions including hemostatic agents,
 - Protocols for rapid reversal of anticoagulants,
 - Assessment of safely recovering and reinfusing shed blood, and
 - Utilization of program defined rapid testing for coagulation management.

PBMPC.13

The program oversees postoperative or postintervention patient care.

Element(s) of Performance for PBMPC.13

1. The program ensures that ~~postoperative or postintervention patients are monitored to determine the need for postoperative transfusion or anemia care.~~
1. The program ensures monitoring of patients post-procedure to determine the need for postoperative transfusion or anemia care, including iron and other micronutrient replenishment.

PBMPC.14

The program has procedures for patients who do not require invasive procedures.

Element(s) of Performance for PBMPC.14

1. The program oversees and reviews the following: ☐ ☐ (D)
- Procedures for identification of patients who decline transfusion.
 - Procedures for ~~identification~~ of patients who may benefit from medications or treatments to minimize the need for allogeneic transfusion.
 - The prescribing and ordering of blood components or alternatives to transfusion.

1. **The program oversees and reviews the following:** ☐ ☐ (D)
- **Procedures for identification of patients who decline transfusion.**
 - **Procedures for identifying patients who may benefit from medications or treatments to minimize the need for allogeneic transfusion.**
 - **The prescribing and ordering of blood components or alternatives to transfusion.**

PBMPC.15

The program has policies, processes, and procedures to manage anemia in nonsurgical inpatients.

Element(s) of Performance for PBMPC.15

1. ~~The program~~, based on activity level, has policies, processes, and procedures in place to manage anemia in nonsurgical inpatients, including patients suffering from iron and/or micronutrient deficiency. ☐ ☐ (D)
 Note: For more information on a program's activity level, refer to Appendix A.

1. **Based on activity level, the program has policies, processes, and procedures in place to manage anemia in nonsurgical inpatients, including patients suffering from iron and/or micronutrient deficiency.** ☐ ☐ (D)
 Note: For more information on a program's activity level, refer to Appendix A.

PBMPC.16

The program has policies, processes, and procedures for obstetric patients.

Element(s) of Performance for PBMPC.16

1. The program oversees and reviews policies, processes, and procedures for obstetric patients including the following: ☐ ☐
- Patients for whom blood is not an option.
 - Identification and management of pregnancies with known risk for hemolytic disease of the fetus and newborn or neonatal alloimmune thrombocytopenia.
 - ~~Prenatal~~ anemia management.

1. **The program oversees and reviews policies, processes, and procedures for obstetric patients including the following:** ☐ ☐
- **Patients for whom blood is not an option.**
 - **Identification and management of pregnancies with known risk for hemolytic disease of the fetus and newborn or neonatal alloimmune thrombocytopenia.**
 - **Antepartum and postpartum anemia management.**

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

2. Postpartum hemorrhage preparedness and management identify the following:
- Quantitative cumulative assessment of maternal blood loss for all patients.
 - Patients with known high-bleeding risk (~~that is,~~ placental abnormalities).
 - Postpartum hemorrhage protocol including predelivery risk assessment, postdelivery patient identification with step-wise process to manage bleeding, massive transfusion protocol, and/or patient transfer.

2. **Postpartum hemorrhage preparedness and management identify the following:**
- **Patients where blood is not an option.**
 - **Quantitative cumulative assessment of maternal blood loss for all patients.**
 - **Patients with known high-bleeding risk (for example, placental implantation abnormalities).**
 - **Postpartum hemorrhage protocol including predelivery risk assessment, postdelivery patient identification with stepwise process to manage bleeding, massive transfusion/massive hemorrhage protocol, and/or patient transfer.**

PBMPC.17

The program has processes and procedures for massive blood loss and emergent care.

Element(s) of Performance for PBMPC.17

2. The program ensures compliance with the processes and procedures for ~~the management and delivery~~ of blood and blood components for patients with emergency blood requirements, including massive blood loss.
2. **The program ensures compliance with the processes and procedures for managing and delivering blood and blood components for patients with emergency blood requirements, including massive blood loss.**

PBMPC.20

The program addresses patient blood management for outpatients.

Element(s) of Performance for PBMPC.20

1. The program oversees and reviews policies or processes to ensure that iron and/or micronutrient deficiency is considered, evaluated, and corrected in patients with red blood cell orders in the outpatient setting.
1. **The program oversees and reviews policies or processes to ensure that iron and/or micronutrient deficiency is considered, evaluated, and corrected in patients with red blood cell transfusion orders in the outpatient setting.**

PBMPC.22

The program reviews performance indicator data.

Element(s) of Performance for PBMPC.22

Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

1. The program obtains and reviews the following data at least quarterly (unless noted): D
- Blood and blood component use.
 - Blood and blood component use appropriateness.
 - Blood administration policy compliance.
 - Blood and blood component wastage and discard, including reasons for unused components.
 - Crossmatch-to-transfusion ratio.
 - Deviation from transfusion service procedures or protocols.
 - Transfusion reactions by ~~type~~.
 - Informed consent for blood transfusion.
 - Massive transfusion protocol use.
 - Single-unit red blood cell transfusion practice performance metric.
 - Use of intraoperative blood recovery equipment and quality control.
 - Anemia program utilization.
 - Iron and micronutrient deficiency identification and management in the outpatient transfusion setting.
 - Blood infusion equipment and warmer(s) maintenance program (annually).
 - External assessment results (for example, AABB, The Joint Commission, or an equivalent accrediting body) (biennially).
- (See also PBAM.03, EP 1)

1. **The program obtains and reviews the following data at least quarterly (unless noted):** D
- **Blood and blood component use.**
 - **Blood and blood component use appropriateness.**
 - **Blood administration policy compliance.**
 - **Blood and blood component wastage and discard, including reasons for unused components.**
 - **Crossmatch-to-transfusion ratio.**
 - **Deviation from transfusion service procedures or protocols.**
 - **Transfusion reactions by category.**
 - **Informed consent for blood transfusion.**
 - **Massive transfusion/massive hemorrhage protocol use.**
 - **Single-unit red blood cell transfusion practice performance metric.**
 - **Use of intraoperative blood recovery equipment and quality control.**
 - **Anemia program utilization.**
 - **Iron and micronutrient deficiency identification and management in the outpatient transfusion setting.**
 - **Blood infusion equipment and warmer(s) maintenance program (annually).**
 - **External assessment results (for example, AABB, The Joint Commission, or an equivalent accrediting body) (biennially).**
 - **Bloodless program enrollment/evaluation of effectiveness.**
- (See also PBAM.03, EP 1)

Process Improvement Through Corrective and Preventive Action (PBMPI) Chapter

PBMPI.02

The program has a process for corrective action.

Element(s) of Performance for PBMPI.02

Key: **D** indicates that documentation is required;

R indicates an identified risk area;

2. The process for corrective action of deviations, nonconformances, and complaints includes the following elements: (D)
- Description of the event.
 - Investigation of the cause.
 - Determination of the corrective action(s).
 - Implementation of correction action(s).
 - Evaluation to ensure that corrective action is taken and that it is effective.
2. **The process for corrective action of deviations, nonconformances, and complaints includes the following elements:** (D)
- **Description of the event.**
 - **Investigation of the cause.**
 - **Determination of the corrective action(s).**
 - **Implementation of correction action(s).**
 - **Evaluation to ensure that corrective action is taken and is effective.**
4. Program findings are reported to the provider(s) by the medical director of the program.
4. **Program findings are reported to the provider(s) by the program's medical director.**

Resources (PBMRS) Chapter

PBMRS.01

Resources are available to perform, verify, and manage program activities.

Element(s) of Performance for PBMRS.01

1. The program has policies, processes, and procedures that ensure the provision of adequate resources to perform, verify, and manage all activities in the oversight and review of patient blood management. (D)
1. **The program has policies, processes, and procedures that ensure adequate resources to perform, verify, and manage all activities in the oversight and review of patient blood management.** (D)

PBMRS.02

Staff are qualified, trained, and competent to perform their responsibilities.

Element(s) of Performance for PBMRS.02

3. Personnel performing critical tasks are qualified to perform assigned activities on the basis of appropriate education, training, and/or experience. (D)
3. **Personnel performing critical tasks are qualified to perform assigned activities based on appropriate education, training, and/or experience.** (D)
6. **Corrective action is taken when competence has not been demonstrated.** (D)
6. Individuals who order and/or transfuse blood meet facility-defined requirements for education related to patient blood management. (D)

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

7. Individuals involved in clinical patient blood management meet facility-defined requirements for education, including evidence-based approaches to improving outcomes focused on patient-centered care. (D)

Suppliers and Customers (PBMSC) Chapter

PBMSC.01

The program evaluates the performance of its suppliers.

Element(s) of Performance for PBMSC.01

1. The program has policies, processes, and procedures to evaluate the ability of suppliers of components and services to ~~consistently~~ meet specified requirements. (D)
 Note: Specified requirements are any requirements in these PBM standards and including, but not limited to, US Food and Drug Administration (FDA) requirements; requirements of a facility's internal policies, processes, and procedures; manufacturers' instructions; customer agreements; practice standards; and requirements of accrediting organizations such as AABB and The Joint Commission.
1. **The program has policies, processes, and procedures to evaluate the ability of suppliers of components and services to meet specified requirements.** (D)
Note: Specified requirements are any requirements in these PBM standards and including, but not limited to, US Food and Drug Administration (FDA) requirements; requirements of a facility's internal policies, processes, and procedures; manufacturers' instructions; customer agreements; practice standards; and requirements of accrediting organizations such as AABB and The Joint Commission.
2. The program evaluates and participates in ~~the selection of~~ suppliers, when possible, before acceptance of an agreement. (D)
2. **The program evaluates and participates in selecting suppliers, when possible, before acceptance of an agreement.** (D)
3. When a supplier fails to meet specified requirements, it is reported to the management with contracting authority.
 Note: Specified requirements are any requirements in these PBM standards and including, but not limited to, US Food and Drug Administration (FDA) requirements; requirements of a facility's internal policies, processes, and procedures; manufacturers' instructions; customer agreements; practice standards; and requirements of accrediting organizations such as AABB and The Joint Commission.
3. **When a supplier fails to meet specified requirements, it is reported to the management with the contracting authority.**
Note: Specified requirements are any requirements in these PBM standards and including, but not limited to, US Food and Drug Administration (FDA) requirements; requirements of a facility's internal policies, processes, and procedures; manufacturers' instructions; customer agreements; practice standards; and requirements of accrediting organizations such as AABB and The Joint Commission.

PBMSC.03

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

The program has written agreements with organizations that provide contracted services.

Element(s) of Performance for PBMSC.03

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|----|---|---|--|--|
| 2. | If any patient blood management activities are performed by a third-party provider, the program is involved in the supplier qualification process. | <table border="1" style="border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> | | |
| | | | | |
| 2. | If a third-party provider performs patient blood management activities, the program is involved in the supplier qualification process. | <table border="1" style="border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> | | |
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